MEDICINOVA INC
Form 10-Q
May 16, 2011
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2011

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
FOR THE TRANSITION PERIOD FROM TO

Commission file number: 001-33185

MEDICINOVA, INC.

(Exact name of registrant as specified in its charter)

Delaware	**33-0927979**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**

4350 La Jolla Village Drive, Suite 950

San Diego, CA	**92122**
(Address of Principal Executive Offices)	**(Zip Code)**

(858) 373-1500

(Registrant s Telephone Number, Including Area Code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ¨ No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a small reporting company. See definition of accelerated filer , large accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	¨	Accelerated filer	¨
Non-accelerated filer	¨ (Do not check if a smaller reporting company)	Smaller reporting company	x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

As of May 10, 2011, the registrant had 15,283,582 shares of Common Stock ($0.001 par value) outstanding.

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MEDICINOVA, INC.

(a development stage company)

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PART I. FINANCIAL INFORMATION

ITEM 1. CONSOLIDATED FINANCIAL STATEMENTS.

MEDICINOVA, INC.

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CONSOLIDATED BALANCE SHEETS

	March 31, 2011 (Unaudited)	December 31, 2010
Assets		
Current assets:		
Cash and cash equivalents	$ 31,379,857	$ 28,252,204
Restricted cash (Note 2)	28,652,977	28,688,892
Restricted investment (Note 2)		623,751
Restricted letter of credit (Note 2)		47
Prepaid expenses and other current assets	848,876	779,103
Total current assets	60,881,710	58,343,997
Goodwill (Notes 1 and 2)	9,600,241	9,600,241
In-process research and development (Note 2)	4,800,000	4,800,000
Property and equipment, net	52,665	65,209
Other assets	103,296	124,722
Total assets	$ 75,437,912	$ 72,934,169
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 873,886	$ 1,099,625
Management transition plan liability (Note 2)		623,751
Debt (Notes 3, 4 and 11)	13,751,932	4,951,610
Convertible notes (Notes 2 and 8)	28,621,640	28,626,296
Escrow holdback (Note 2)	47	47
Accrued expenses	2,566,072	1,133,273
Income taxes payable	1,379	6,847
Accrued compensation and related expenses	502,011	348,755
Total current liabilities	46,316,967	36,790,204
Deferred tax liability (Note 2)	1,956,000	1,956,000
Long-term debt, less current portion (Notes 3, 4 and 11)		9,483,605
Total liabilities	48,272,967	48,229,809
Commitments and contingencies (Note 9)		
Stockholders equity:		
Preferred stock, $0.01 par value; 500,000 shares authorized at March 31, 2011 and December 31, 2010; no shares outstanding at March 31, 2011 and December 31, 2010		
Common stock, $0.001 par value; 30,000,000 shares authorized at March 31, 2011 and December 31, 2010; 15,290,839 and 12,482,867 shares issued at March 31, 2011 and	15,291	12,484

December 31, 2010, respectively, and 15,248,930 and 12,439,132 shares outstanding at March 31, 2011 and December 31, 2010, respectively		
Additional paid-in capital	301,601,079	293,483,920
Accumulated other comprehensive loss	(63,359)	(55,702)
Treasury stock, at cost; 41,909 shares at March 31, 2011 and 43,735 shares at December 31, 2010	(1,193,930)	(1,197,935)
Deficit accumulated during the development stage	(273,194,136)	(267,538,407)
Total stockholders equity	27,164,945	24,704,360
Total liabilities and stockholders equity	$ 75,437,912	$ 72,934,169

See accompanying notes.

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MEDICINOVA, INC.

(a development stage company)

CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three months ended March 31,		Period from September 26, 2000 (inception) to March 31,
	2011	2010	2011
Revenues	$	$	$ 1,558,227
Operating expenses:			
Cost of revenues			1,258,421
Research and development	2,623,898	2,949,456	156,880,742
General and administrative	2,352,476	2,286,952	99,551,285
Total operating expenses	4,976,374	5,236,408	257,690,448
Operating loss	(4,976,374)	(5,236,408)	(256,132,221)
Impairment charge on investment securities		(7,479)	(1,735,212)
Foreign exchange gain/(loss)	358	(3,746)	(97,468)
Other expense	(52,733)	(31,307)	(233,240)
Interest expense	(652,387)	(44,174)	(2,663,112)
Other income	25,406	161,113	19,083,483
Income taxes		751	(53,244)
Net loss	(5,655,730)	(5,161,250)	(241,831,014)
Accretion to redemption value of redeemable convertible preferred stock			(98,445)
Deemed dividend resulting from beneficial conversion feature on Series C redeemable convertible preferred stock			(31,264,677)
Net loss applicable to common stockholders	$ (5,655,730)	$ (5,161,250)	$ (273,194,136)
Basic and diluted net loss per common share	$ (0.45)	$ (0.42)	
Shares used to compute basic and diluted net loss per common share	12,547,759	12,269,102	

See accompanying notes.

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MEDICINOVA, INC.

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CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Three months ended March 31,		Period from September 26, 2000 (inception) to March 31,
	2011	2010	2011
Operating activities:			
Net loss	$ (5,655,730)	$ (5,161,250)	$ (241,831,015)
Adjustments to reconcile net loss to net cash used in operating activities:			
Non-cash stock-based compensation	175,683	538,485	48,484,215
Depreciation and amortization	12,544	41,027	1,916,099
Amortization of premium/discount on investment securities, convertible notes and debt discount and issuance costs	227,068	31,307	(1,624,416)
Impairment charge/(gain), net on investment securities and ARS put		7,479	1,735,212
(Gain)/loss on disposal of assets		2,026	10,637
Impairment of sublease			35,259
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	(69,773)	(178,610)	(811,927)
Accounts payable, accrued expenses, income taxes payable and deferred rent	1,193,935	136,912	3,171,669
Accrued compensation and related expenses	153,256	(862,137)	405,870
Restricted assets		(143,159)	5,999
Net cash used in operating activities	(3,963,017)	(5,587,920)	(188,502,398)
Investing activities:			
Cash paid for acquired business, net of acquired cash			(2,829,785)
Purchases of investment securities			(377,205,766)
Maturities or sales of investment securities		3,394,193	377,918,240
Acquisition of property and equipment		(7,101)	(2,271,505)
Proceeds from sales of property and equipment			256,845
Net cash provided by (used in) investing activities		3,387,092	(4,131,971)
Financing activities:			
Net proceeds from the sale of common stock	5,025,381	250	126,488,903
Net proceeds from the sale of warrants	2,882,258		2,882,258
Sale of preferred stock, net of issuance costs			80,216,971
(Repayments of) proceeds from ARS loan, net		(3,162,119)	
(Repayments of) proceeds from debt, net	(857,619)		13,812,381
Proceeds from conversion of convertible notes	36,645	1,695,466	1,841,425
Purchase of treasury stock, net of employee stock purchases	4,005	23,107	(1,227,712)
Net cash provided by financing activities	7,090,670	(1,443,296)	224,014,226
Net increase (decrease) in cash and cash equivalents	3,127,653	(3,644,124)	31,379,857
Cash and cash equivalents, beginning of period	28,252,204	19,241,581	
Cash and cash equivalents, end of period	$ 31,379,857	15,597,457	$ 31,379,857
Supplemental disclosure of non-cash financing and operating activities:			
Conversion of convertible preferred stock into common stock upon IPO	$	$	$ 43,515,677

Restricted assets, cash unrestricted upon conversion of convertible notes	$ 36,670	$ 1,695,466	$ 1,842,012
Supplemental disclosures of cash flow information:			
Income taxes paid	$ 5,468	$ 8,795	$ 52,108
Interest paid	$ 478, 051	$ 44,174	$ 1,876,468

See accompanying notes.

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MEDICINOVA, INC.

(a development stage company)

Notes to Consolidated Financial Statements

(Unaudited)

1. Interim Financial Information

The Company

We were incorporated in the state of Delaware in September 2000. We are a development stage biopharmaceutical company focused on acquiring and developing novel, small molecule therapeutics for the treatment of diseases with unmet need with a specific focus on the U.S. market. Through strategic alliances primarily with Japanese pharmaceutical companies, we hold rights to a diversified portfolio of clinical and preclinical product candidates, each of which we believe has a well-characterized and differentiated therapeutic profile, attractive commercial potential and patent assets having claims of commercially adequate scope.

On March 3, 2011, we executed a joint venture letter of intent with Zhejiang Medicine Co., Ltd. and Beijing Make-Friend Medicine Technology Co., Ltd., which provides for the establishment of a joint venture company to develop and commercialize MN-221 in China.

Basis of Presentation

We have prepared the accompanying unaudited consolidated financial statements in accordance with accounting principles generally accepted in the United States of America for interim financial information. Accordingly, they do not include all of the information and disclosures required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation of the financial position, results of operations and cash flow for the interim period presented have been included. Operating results for the three months ended March 31, 2011 are not necessarily indicative of the results that may be expected for the year ending December 31, 2011 or for any other period. For further information, see the financial statements and disclosures thereto for the year ended December 31, 2010 in our Annual Report on Form 10-K as filed with the Securities and Exchange Commission on March 31, 2011.

Principles of Consolidation

The consolidated financial statements include the accounts of MediciNova, Inc. and its wholly-owned subsidiaries. MediciNova, Inc. and its subsidiaries are collectively referred to herein as we, our or us.

On December 13, 2006, MediciNova (Europe) Limited, a wholly-owned subsidiary of MediciNova, Inc., was incorporated under the laws of England and Wales and established for the purpose of facilitating the clinical development of the Company s compounds for the European marketplace. MediciNova (Europe) Limited s functional currency is the U.S. dollar, the reporting currency of its parent.

On January 4, 2007, MediciNova Japan, Inc., a wholly-owned subsidiary of MediciNova, Inc., was incorporated under the laws of Japan and established to strengthen business development and investor and public relations activities in Japan and other Asian countries. MediciNova Japan, Inc. s functional currency is the Japanese Yen.

On August 17, 2009, Absolute Merger, Inc., a wholly-owned subsidiary of MediciNova, Inc. was incorporated under the General Corporation Law of the State of Delaware for the purpose of facilitating the Merger (the Merger) with Avigen, Inc. (Avigen). On December 18, 2009, Absolute Merger, Inc. merged with and into Avigen, with Avigen continuing as the surviving entity and wholly-owned subsidiary of ours.

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All intercompany transactions and investments in our subsidiaries have been eliminated in consolidation.

Use of Estimates

We prepared the accompanying unaudited consolidated financial statements in conformity with accounting principles generally accepted in the United States of America, which requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results may differ from those estimates.

Concentrations and Uncertainties

We maintain cash balances at various financial institutions and such balances commonly exceed the $250,000 insured amount by the Federal Deposit Insurance Corporation. We also maintain money market funds at various financial institutions which are not federally insured. We have not experienced any losses in such accounts and management believes that we are not exposed to any significant credit risk with respect to such cash and cash equivalents.

We have sustained operating losses since inception and expect such losses to continue over the next several years. We believe our existing cash and cash equivalents at March 31, 2011, will be sufficient to fund all of our debt repayment obligations, our forecasted research and development expenses and our fixed contractual obligations over the next 12 months. However, we will need to successfully complete one or more additional financing transactions and/or corporate partnerships in the near-term; otherwise, we will not have sufficient cash or other liquidity to fund our operations as currently conducted and staffed for the following 12 months, which raises substantial doubt as to our ability to continue as a going concern. The accompanying consolidated financial statements have been prepared assuming that we will continue as a going concern. If adequate funds are not available, we will be required to delay, reduce the scope of or terminate one or more of our product development programs and relinquish some or all rights to product candidates. In parallel, we would be required to implement another reduction-in-force, implement additional cost reduction measures related to compensation and employee benefits, and reduce our professional fees and travel spend to minimize operating costs, to offset the lack of available funding.

Reclassifications

Certain amounts in the consolidated statements of operations for the three month period ended March 31, 2010 have been reclassified to conform to the presentation of interest expense, other expense and other income as reclassified in May 2010.

2. Avigen Transaction

On December 18, 2009, Absolute Merger, Inc., a wholly-owned subsidiary of ours, merged with and into Avigen, with Avigen continuing as the surviving entity and wholly-owned subsidiary of ours. Under the terms of the merger, we issued $29.4 million in secured convertible notes that mature on June 18, 2011, the 18-month anniversary of the closing of the merger. Holders of these convertible notes may convert their notes into our common stock at an initial conversion price of $6.80 per share. At the maturity of the convertible notes, the remaining holders would be paid out the same per share amount as the Avigen shareholders that elected to receive cash at the merger closing, plus accrued interest. As part of the merger consideration, the former Avigen shareholders were also entitled to receive approximately $0.04 per share, which was paid in two increments in 2010, and rights under contingent payment rights issued as part of the merger consideration. The amount paid in the two installments was net of a reconciliation of Avigen expenses and a letter of credit after expiry. In fiscal year 2010, under the first and second installments, we paid $140,119 and $73,449, respectively, to Avigen shareholders who elected payment in cash and we issued an additional principal amount of $685,917 and

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$359,551, respectively, in convertible notes to Avigen shareholders who elected payment in convertible notes in lieu of a cash payment. The primary reasons for the Avigen acquisition were to combine the ibudilast development programs each company was respectively pursuing, to utilize the preclinical and clinical data for AV411 as support for the development pathway of MN-166, resulting in cost savings for us, and to capture a potential financing opportunity given Avigen s cash balance prior to the Merger.

The following table reconciles the December 31, 2010 carrying value of the acquisition related assets and liabilities with their respective balances at March 31, 2011:

	Carrying Value at 12/31/10	Value of Notes Converted 1/1/11-3/31/11(9)	Interest Earned 1/1/11-3/31/11(10)	Interest Expense (Accretion) 1/1/11-3/31/11(11)	Other Activity 1/1/11-3/31/11	Carrying Value at 3/31/2011
Restricted cash(1)	$ 28,688,892	$ (36,670)	$ 708	$	$ 47(3)	$ 28,652,977
Restricted investment-MTP(2)	$ 623,751	$	$ 10	$	$ (623,761)(2)	$
Restricted letter of credit(3)	$ 47	$	$	$	$ (47)(3)	$
IPR&D(4)	$ 4,800,000	$	$	$	$	$ 4,800,000
Goodwill(5)	$ 9,600,241	$	$	$	$	$ 9,600,241
Escrow holdback(6)	$ (47)	$	$	$	$	$ (47)
MTP liability(2)	$ (623,751)	$	$ (10)	$	$ 623,761(2)	$
Deferred tax liability(7)	$ (1,956,000)	$	$	$	$	$ (1,956,000)
Convertible notes(8)	$ (28,626,296)	$ 36,670	$ (708)	$ (31,306)	$	$ (28,621,640)

(1) Restricted cash consists of cash held in a separate trust account, managed by a third-party, in connection with the Avigen merger consideration.

(2) Restricted investment consisted of cash held in an irrevocable grantor trust, or rabbi trust, which was intended to fund benefit obligations under the Avigen, Inc. Management Transition Plan, or MTP. These funds represented reserves for benefits eligible to terminated employees as defined by the MTP. Accordingly, we booked the associated MTP liability. During the first quarter of 2011, the Avigen Representative notified us of his termination of the MTP due to the fulfillment of its obligations. Upon termination of the trust, the remaining funds in the account were paid to the former Avigen stockholders on a pro rata basis, which relieved us of the MTP liability.

(3) Restricted letter of credit consisted of cash provided as a credit guarantee and security for an irrevocable letter of credit related to Avigen s original lease of office space which expired November 30, 2010. The $47 remaining in the account related to December 2010 interest which posted after the funds were transferred to the escrow holdback account for distribution. These funds were transferred to the restricted cash account in January 2011.

(4) In-process research and development (IPR&D) represents an estimate of fair value of in-process technology related to Avigen s AV411 program, which at the merger closing date, had not received U.S. Food and Drug Administration (FDA) approval for any indication. As such, pursuant to ASC 805, amortization of the IPR&D will not occur until it reaches market feasibility. The annual test date for IPR&D impairment is December 31.

(5) We included in the purchase price of Avigen the fair value of the aggregate merger consideration. We recorded $9.6 million of goodwill related to the excess purchase price over the assigned values of the net assets acquired. The goodwill was primarily a direct result of the fair value of the conversion feature of the convertible notes. The annual test date for goodwill impairment is December 31.

(6) At the closing of the merger, we and Avigen funded $1,500,000 in a combination of cash and a letter of credit in a separate escrow account, pursuant to an escrow agreement, to cover the escrow holdback liability. During fiscal year 2010, pursuant to the terms of the escrow agreement, the escrow holdback liability was released upon distribution of the escrow funds to the Avigen shareholders on a pro rate basis, in either cash or convertible notes, depending on the election made at the acquisition date. The remaining $47 liability relates to the last interest payment in December that was not distributed to the Avigen shareholders.

(7) The deferred tax liability represents the book to tax basis difference related to IPR&D acquired through the acquisition of Avigen.

(8) At the closing of the merger, we and American Stock Transfer & Trust Company, LLC, as trustee, entered into an indenture governing the terms of the convertible notes. Under the terms of a separate trust agreement, $29.4 million was deposited with a trust agent for the benefit of the holders and us. At the election of the respective convertible note holders, the convertible notes can be converted into our common stock at the conversion price of $6.80 per share. Upon maturity of the convertible notes on June 18, 2011, the 18-month anniversary of the closing of the merger, we will use the funds remaining in the separate trust to pay the principal amount of, and accrued interest on, the remaining convertible notes. For the three months ended March 31, 2011, $708 was

the amount of interest capitalized on the convertible notes.

(9) During the three months ended March 31, 2011, 5,389 shares of our common stock were issued in connection with the conversion of convertible notes to our common stock at a conversion price of $6.80. $36,670 includes fractional shares being paid out of restricted cash. The proceeds received as a result of the convertible notes conversions into our common stock were deposited into a money market account and recorded as cash and cash equivalents in our consolidated balance sheet at March 31, 2011.

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(10) Interest earned on the restricted cash, investment and letter of credit balances is added to the principal of the respective liability accounts.

(11) At December 31, 2009, the fair value of the convertible notes was less than their face value. As a result, over the term of the convertible notes (18 months) we will accrete the discount on the convertible notes with the offset being charged to interest expense.

See Notes to Consolidated Financial Statements Note 2, Avigen Transaction, in our Annual Report on Form 10-K for further information on the Avigen merger.

3. Fair Value Measurements Other Than Intangibles and Goodwill

As defined in the authoritative guidance for fair value measurements and disclosures under ASC 820 (formerly SFAS No. 157), fair value is based on the price that would be received to sell an asset or would be paid to transfer a liability in an orderly transaction between market participants at the measurement date. To increase the comparability and consistency of fair value measurements, ASC 820 prescribes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels which are described below:

Level 1:	Inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities at the measurement date.
Level 2:	Inputs are quoted prices for similar items in active markets or inputs are quoted prices for identical or similar items in markets that are not active.
Level 3:	Inputs are unobservable due to little or no market data availability and inputs are usually developed by management or a third-party which reflect those inputs that a market participant would use. The fair value hierarchy gives the lowest priority to Level 3 inputs.

At March 31, 2011, cash and cash equivalents (instruments with maturities of three months or less at the date of purchase) were $31.4 million, which were invested in money market accounts and money market funds. At March 31, 2011, restricted cash was $28.7 million and primarily invested in money market funds. We measure our cash equivalents and restricted cash on a recurring basis and the fair value of these current assets is based on Level 1 criteria in which their carrying amount is a reasonable estimate of their fair value based on daily quoted market prices.

The following table presents our financial instruments measured at fair value on a non-recurring basis classified by the fair value measurements and disclosures valuation hierarchy:

	As of March 31, 2011			
		Fair Value Measurements Using		
	Total	Level 1	Level 2	Level 3
Current liabilities:				
Debt(3)	$ 13,751,932	$	$	$ 13,751,932
Convertible notes(1, 2)	28,621,640			28,621,640
Total current liability	$ 42,373,572	$	$	$ 42,373,572

(1) The fair value of the convertible notes and its related conversion feature were based on a binomial option pricing model (BOPM). Assumptions used in the BOPM included the maturity date of the convertible notes, the time between nodes, volatility, the face value of the convertible notes at the merger closing date and the risk-free rate. See Notes to Consolidated Financial Statements Note 2, Avigen Transaction in our Annual Report on Form 10-K for further information on the BOPM.

(2) Although we recorded the convertible notes as a liability upon merger closing on December 18, 2009, following ASC 805, the fair value of the conversion feature was accounted for within equity and will not be re-measured during interim periods and subsequent settlements (conversions to our stock) will be accounted for in equity. See Note 2, Avigen Transaction, above for information on the activity impacting the convertible notes liability during the three months ended March 31, 2011.

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(3) The carrying value of the debt approximates fair value. See Notes to Consolidated Financial Statements Note 4, Debt, below for further information regarding the debt.

4. Debt

On May 10, 2010, we entered the Loan Agreement with Oxford, under which we borrowed $15.0 million. The stated interest rate on the loan was 12.87 percent. The effective interest rate on the debt financing was calculated to be 18.14 percent.

Our obligations under the Loan Agreement are secured by a first priority security interest in substantially all of our assets, other than our intellectual property. We also have agreed not to pledge or otherwise encumber our intellectual property assets. Our obligations under the Loan Agreement are guaranteed on a senior secured basis by Avigen.

In addition, the Loan Agreement contains covenants that restrict our ability to:

incur additional indebtedness;

create liens;

enter into certain merger and licensing transactions;

dispose of certain of our assets;

enter into certain fundamental corporate changes;

make certain types of investments; and

make certain payments and distributions.

The Loan Agreement required that on or before March 31, 2011 we must have either (i) entered into a collaboration, joint venture or partnership with a non-affiliate providing for up-front cash proceeds to us (with such proceeds received on or before March 31, 2011) of not less than $15.0 million from either or a combination of an upfront payment(s) or proceeds from the sale or conversion of our securities issued in connection therewith or (ii) received positive Phase 2b data on MN-221, as defined in a completed partnership or joint venture agreement relating to MN-221, or had a positive end-of-Phase 2 meeting with the FDA and obtained the approval of the board of directors to proceed to Phase 3 with MN-221. A failure to meet the Loan Agreement requirements by March 31, 2011, would result in an immediate requirement for Loan repayment (as well as an increase in interest rate). In anticipation of not achieving either of the affirmative covenants required under our loan agreement with Oxford by March 31, 2011, we executed a pay-off letter between us and Oxford dated March 31, 2011, in which we negotiated the repayment of the loan in full on April 1, 2011. Oxford agreed to waive the early payment penalty of approximately $437,000. As a result of the executed loan payoff letter, we have classified the entire debt obligation as a current liability in our consolidated balance sheet as of March 31. 2011. See Notes to Consolidated Financial Statements Note 11, Subsequent Events, for further information on the Oxford loan payoff.

In connection with the Loan Agreement, we issued to Oxford a warrant to purchase up to 198,020 shares of our common stock. This warrant is exercisable, immediately, in whole or in part, has a per share exercise price of $6.06 and may be exercised on a cashless basis. The warrant will terminate on the earlier of May 10, 2017 or the closing date of a merger or consolidation transaction in which we are not the surviving entity. In addition, the warrant and debt instrument are immediately separable and were issued separately; thus, we accounted for the warrant as a component of stockholders equity as the agreement requires settlement in shares and under no provision of the agreement are we required to settle the warrant in cash.

We accounted for the interest on the debt using the effective interest method wherein we treated the debt issuance costs paid directly to the lender (financing fees) and the relative fair value of the warrants issued to the

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lender as a discount on the debt (or a contra liability) and we treated the debt issuance costs paid to third parties (primarily legal fees) as an other asset in our consolidated balance sheet. The amortization of the debt discount is recorded as interest expense and the amortization of the debt issuance costs paid to third parties is recorded as other expense in our consolidated statement of operations. The table below summarizes the debt activity recorded during the three months ended March 31, 2011:

	Carrying Value 12/31/2010	Amortization (Interest Expense)	Amortization (Other Expense)	Repayments	Carrying Value 3/31/2011
Other Assets:					
Debt issuance costs paid to third parties	$ 124,722	$	$ (21,426)	$	$ 103,296
Liability:					
Loan	$ (15,000,000)	$	$	$ 857,619	$ (14,142,381)
Deferred interest charge	(134,491)	(54,207)			(188,698)
	$ (15,134,491)	$ (54,207)	$	$ 857,619	$ (14,331,079)
Contra Liability:					
Relative fair value of warrants issued to lender(1)	$ 595,342	$ (102,274)	$	$	$ 493,068
Debt issuance costs paid to lender	103,934	(17,855)			86,079
	$ 699,276	$ (120,129)	$	$	$ 579,147

(1) The relative fair value of the warrants issued to the lender was calculated using a Black-Scholes valuation model. The risk-free interest rate assumption used is 2.86 percent and is based upon observed risk-free interest rates appropriate for the expected term of the warrants. The expected volatility assumption used is 76 percent and is consistent with the volatility of our common stock based on the historical volatility of our stock since listing on the Nasdaq Global Market in December 2006. We have not paid any dividends on our common stock since our inception, and we do not anticipate paying any dividends on our common stock in the foreseeable future. Therefore, the dividend yield assumption used is zero. The expected term assumption used is seven years, which is the contractual life of the warrants. The fair value of the warrants using Black-Scholes is calculated to be $4.34 per share.

5. Net Loss Per Share

Net loss per share is presented as basic and diluted net loss per share. Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted average number of common stock equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, convertible preferred stock, stock options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive. For the three months ended March 31, 2011 and March 31, 2010, 83,957 and 4,471,246, respectively, potentially dilutive securities were excluded from determining diluted earnings per share because of their anti-dilutive effect.

6. Comprehensive Income (Loss)

The authoritative guidance for comprehensive income under ASC 820 (formerly SFAS No. 130) requires that all components of comprehensive income (loss), including net income (loss), be reported in the financial statements in the period in which they are recognized. Comprehensive income (loss) is defined as the change in equity (net assets) during a period from transactions and other events and circumstances from non-owner sources.

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Net income (loss) and other comprehensive income (loss), including foreign currency translation adjustments and unrealized gains and losses on investments, are reported, net of their related tax effect, to arrive at comprehensive income (loss). Our comprehensive loss includes unrealized losses on marketable securities and currency translation. The table below sets forth the components of our accumulated other comprehensive loss at:

	March 31, 2011	March 31, 2010
Beginning balance	$ (55,702)	$ (64,914)
Currency translation	(7,657)	(1,222)
Ending balance	$ (63,359)	$ (66,136)

As of March 31, 2011 and 2010, our comprehensive loss was $5,663,387 and $5,162,472, respectively.

7. Share-Based Payments

For the three months ended March 31, 2011 and 2010, share-based compensation expense related to stock options of approximately $130,000 and $400,000, respectively, was recorded as a component of general and administrative expense, and approximately $45,000 and $90,000, respectively, was recorded as research and development expense.

During the three months ended March 31, 2011, stock options to purchase 1,917 shares of common stock were exercised for approximately $8,200. As of March 31, 2011, there was $1.5 million of unamortized compensation cost related to unvested stock option awards, which is expected to be recognized over a remaining weighted-average vesting period of 2.4 years.

There were no options granted during the three months ended March 31, 2011. The exercise price of stock options to purchase 400,000 shares of common stock granted during the three months ended March 31, 2010, was equal to market value on the date of grant and the share-based compensation expense for such stock options is reflected in operating results for the three months ended March 31, 2010. The estimated fair value of each stock option award was determined on the date of grant using the Black-Scholes option valuation model with the following weighted-average assumptions for stock option grants:

	Three Months Ended March 31, 2010
Risk-free interest rate	1.38%
Expected volatility of common stock	76.63%
Dividend yield	0.00%
Expected option term (in years)	4.4

The risk-free interest rate assumption is based upon observed interest rates appropriate for the expected term of our outstanding stock options. The expected volatility of our common stock is based on the historical volatility of our stock since listing on the Nasdaq Global Market in December 2006. We have not paid any dividends on our common stock since our inception, and we do not anticipate paying any dividends on our common stock in the foreseeable future. The expected term of employee stock options is based on the simplified method for plain vanilla options as provided by the authoritative guidance on stock compensation, as we concluded that our historical stock option exercise experience does not provide a reasonable basis for us to estimate the expected term.

As share-based compensation expense recognized in the accompanying consolidated statement of operations for the three months ended March 31, 2011 was based on stock option awards ultimately expected to vest, such expense should be reduced for estimated forfeitures. The authoritative guidance for compensation under ASC 718 (formerly SFAS No. 123R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. We have very few employees and our

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stock options vest monthly; therefore, we did not estimate any forfeitures during the first quarter of 2011, and we will adjust our stock-based compensation expense should any forfeitures occur. The weighted-average fair value of each stock option granted during the three months ended March 31, 2010, estimated as of the grant date using the Black-Scholes option valuation model, was $4.34 per stock option.

8. Income Taxes

In accordance with the authoritative guidance for income taxes under ASC 740 (formerly SFAS No. 109), a deferred liability is determined based on the difference between the financial statement and the tax basis of assets and liabilities as measured by the enacted tax rates, which will be in effect when these differences reverse. We provide a valuation allowance against net deferred assets unless, based upon the available evidence, it is more likely than not that the deferred tax assets will be realized.

Our practice is to recognize interest and/or penalties related to income tax matters in income tax expense. We had no accrued interest or penalties at March 31, 2011 and we have not recorded any uncertain income tax benefits at March 31, 2011.

9. Commitments and Contingencies

Legal Proceedings

On March 3, 2011, we received a legal letter from a former employee who had been terminated in January 2011 pursuant to our planned reduction-in-force to save costs. The legal letter did not assert a claim outright; however, there were allegations made in the legal letter that could threaten litigation against us. We have engaged legal counsel in connection with the possibility of a lawsuit given this legal letter and the fact that this former employee s separation agreement has expired. Given the inherent uncertainty and unpredictability of litigation and due to the status of this legal action, no range of loss or possible loss can be reasonably estimated. However, we do not expect the outcome of this matter to have a material adverse effect on our consolidated financial statements.

We may become involved in various disputes and legal proceedings which arise in the ordinary course of business. While it is not possible to accurately predict or determine the outcome of these matters, an adverse result in any of these matters may occur which could harm our business.

10. Stockholders Equity

Stock Options

We currently grant stock options to our employees, officers, directors and consultants under the 2004 Plan, the successor to the 2000 Plan. No additional stock options have been or will be issued under the 2000 Plan subsequent to our initial public offering. However, the stock options previously granted under the 2000 Plan will remain outstanding until the earlier of expiration or exercise.

A summary of the changes in stock options outstanding under the 2000 Plan and 2004 Plan during the three months ended March 31, 2011 is as follows:

	Stock Options	Weighted Average Exercise Price
Balance at December 31, 2010	2,280,931	$ 8.38
Granted		$
Exercised	(1,917)	$ 4.30
Cancelled	(177,213)	$ 6.69
Balance at March 31, 2011	2,101,801	$ 8.52

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The aggregate intrinsic value of stock options exercised during the three months ended March 31, 2011 was $933. The aggregate intrinsic value of stock options outstanding at March 31, 2011 and exercisable at March 31, 2011 was approximately $80,000 and approximately $48,000, respectively. Of the total stock options outstanding as of March 31, 2011, options to purchase 1,633,483 shares of common stock are exercisable, with a weighted average exercise price of $ 9.34 per share and a weighted average contractual life of 6.0 years.

Employee Stock Purchase Plan (ESPP)

The following assumptions were used to value the March 31, 2011 employee stock purchases: a risk-free interest rate of 0.16 percent, expected volatility of 78 percent, expected term of six months and a dividend rate of 0 percent. For the three months ended March 31, 2011, 1,826 shares of common stock were issued under the ESPP and 272,301 shares of common stock were available for future issuance.

Convertible Notes

Holders of the convertible notes may submit conversion notices, which are irrevocable, instructing the trustee to convert such convertible notes into shares of our common stock at an initial conversion price of $6.80 per share. Following each conversion date, which date generally is the final business day of each calendar month, we will issue the number of whole shares of common stock issuable upon conversion as promptly as practicable (and in any event within 10 business days). The trustee will in turn release to us the respective amount of restricted cash to cover the stock issuance. We will then invest the unrestricted cash into either a money market fund or a money market account. Any fractional shares (after aggregating all convertible notes being converted by a holder on such date) will be rounded down and we will deliver cash for the current market value of the fractional share. For the three months ended March 31, 2011, approximately $36,645 of convertible notes was converted into 5,389 shares of our common stock.

Firm Commitment Underwritten Public Offering

On March 23, 2011, we announced a firm-commitment underwritten public offering of 2,750,000 units at a price to the public of $3.00 per unit for gross proceeds of $8.25 million. Each unit consists of one share of common stock, and a warrant to purchase one share of common stock. The shares of common stock and warrants are immediately separable and were issued separately. The warrants are exercisable immediately upon issuance, have a five-year term and an exercise price of $3.56 per share. On March 24, 2011, the underwriter exercised 50,666 units of its 412,500 unit overallotment. On March 29, 2011, we received net proceeds of approximately $7.9 million, after underwriter discount and underwriter expenses and no warrants exercised. In accordance with the authoritative guidance, we concluded that the warrants were indexed to our stock and do not permit net-cash settlement. Therefore, the warrants were classified as equity instruments and are not being marked to market prospectively as long as they continue to meet the conditions for equity classification.

11. Subsequent Events

Oxford Loan Update

Pursuant to the Oxford loan payoff agreement executed on March 31, 2011, we paid Oxford approximately $15.2 million on April 1, 2011 which paid the loan off in full.

ATM Offering

On May 5, 2011, we entered into an at-the-market issuance sales agreement, or sales agreement, with McNicoll, Lewis & Vlak LLC, or MLV, pursuant to which we may issue and sell shares of our common stock having an aggregate offering price of up to $15.0 million from time to time through MLV as our sales agent. The issuance and sale of these shares by us under the sales agreement, if any, is subject to the effectiveness of our shelf registration statement on Form S-3 (File No. 333-163116), initially filed with the Securities and Exchange Commission on November 13, 2009.

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ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited consolidated financial statements and notes thereto included in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto as of and for the year ended December 31, 2010 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 31, 2011. Past operating results are not necessarily indicative of results that may occur in future periods.

This Quarterly Report on Form 10-Q contains forward-looking statements that are subject to risks and uncertainties, many of which are beyond our control. Our actual results may differ from those anticipated in these forward-looking statements as a result of various factors, including those set forth in Part II of this Quarterly Report on Form 10-Q under the caption Item 1A. Risk Factors and under the caption Item 1A. Risk Factors in our Annual Report on Form 10-K, and the differences may be material. Forward-looking statements discuss matters that are not historical facts. Forward-looking statements include, but are not limited to, statements regarding our plans, strategies, objectives, development programs, clinical trials, industry, financial condition, liquidity and capital resources, future performance and other statements that are not historical facts. Such forward-looking statements include statements preceded by, followed by or that otherwise include the words may, might, will, intend, should, could, can, would, expect, believe, estimate, anticipate, predict, potential, plan or similar words. For such statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. You should not rely unduly on these forward-looking statements, which speak only as of the date hereof. We undertake no obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

Overview and Recent Developments

We are a biopharmaceutical company focused on acquiring and developing novel, small molecule therapeutics for the treatment of diseases with unmet medical need with a specific focus on the U.S. market. Through strategic alliances, primarily with Japanese pharmaceutical companies, we hold rights to a diversified portfolio of clinical and preclinical product candidates, each of which we believe has a well-characterized and differentiated therapeutic profile, attractive commercial potential and patent assets having claims of commercially adequate scope. We were incorporated in Delaware in September 2000.

We are a development stage company. We have incurred significant net losses since our inception. At March 31, 2011, from inception, our accumulated deficit was approximately $273.2 million, including $48.5 million of non-cash stock-based compensation charges related to employee stock-based compensation and founders warrants. We expect to incur substantial net losses for at least the next several years as we continue to develop certain of our existing product development programs, primarily MN-221 for the treatment of acute exacerbations of asthma and Chronic Obstructive Pulmonary Disease, or COPD, exacerbations, and over the long-term if we are successful in expanding our research and development programs and acquiring or in-licensing products, technologies or businesses that are complementary to our own.

We have acquired licenses to eight compounds for the development of ten product candidates. Our development pipeline consists of eight product development programs which have been in clinical development for the treatment of acute exacerbations of asthma, MS, bronchial asthma, IC, solid tumor cancers, Generalized Anxiety Disorders/insomnia, preterm labor and urinary incontinence, and two product development programs which have been in preclinical development for the treatment of thrombotic disorders. In addition, we have expanded our development program for MN-221 for the treatment of COPD exacerbations.

In December 2009 we acquired Avigen Inc., or Avigen, a biopharmaceutical company that focused on identifying and developing differentiated products to treat patients with serious disorders, whose potential

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product candidate was AV411, a macrophage migration inhibitory factor and a glial attenuator for central nervous system, or CNS, disorders, such as neuropathic pain, opioid withdrawal and methamphetamine addiction. We continue to integrate the two ibudilast-based product development programs and pursue discussions with potential partners to secure a strategic collaboration to advance clinical development of the combined development programs.

At present, we are focusing our resources on the following prioritized product development programs:

- MN-221 for the treatment of acute exacerbations of asthma and COPD exacerbations, for which we initiated a Phase 2 clinical trial in the first quarter of 2009 to evaluate the safety and efficacy of MN-221 in patients with severe, acute exacerbations of asthma treated in the emergency room, which is on-going, and initiated a Phase 1b clinical trial in the fourth quarter of 2009 to evaluate the safety of MN-221 at planned escalating doses in patients with stable, moderate to severe COPD, in which we announced preliminary positive results in the first quarter of 2010.

- MN-166/AV411, for which we continue to integrate the two programs into a combined ibudalist-based product development program to pursue discussions with potential partners to secure a strategic collaboration. For MN-166 for the treatment of MS, we completed a Phase 2 clinical trial in Eastern Europe in the second quarter of 2008 and we completed of a monkey toxicity preclinical study in the second quarter of 2010. For AV411 for other CNS disorders, we completed in the third quarter of 2010 a Phase 1b/2a opioid withdrawal clinical trial funded by the National Institute on Drug Abuse, or NIDA, and we have Phase 1b NIDA-funded clinical trial in methamphetamine-dependent volunteers initiated in fourth quarter of 2010.

Upon completion of proof-of-concept Phase 2 clinical trials, we intend to enter into strategic alliances with leading pharmaceutical or biotech companies to support further clinical development, and plan to keep certain commercialization rights in select markets. In addition, we continue to limit development activities for the balance of our existing product candidates in order to focus on our prioritized programs. For each of these remaining product candidates, we plan to conduct development activities only to the extent deemed necessary to maintain our license rights or maximize its value while pursuing a variety of initiatives to monetize such product candidate on appropriate terms.

Our eight non-prioritized product development programs consist of the following:

- MN-001 for the treatment of bronchial asthma, for which we initiated a Phase 3 clinical program in the fourth quarter of 2006 that we subsequently terminated in the second quarter of 2007, and for which we developed prototypes of once-per-day oral dosing formulations;

- MN-001 for the treatment of interstitial cystitis, for which we completed a Phase 2 clinical trial in the first quarter of 2007;

- MN-029 for the treatment of solid tumors, for which we completed one Phase 1 clinical trial in the second quarter of 2006 and one Phase I clinical trial in the fourth quarter of 2007;

- MN-305 for the treatment of Generalized Anxiety Disorder/insomnia, for which we completed a Phase 2 clinical trial for the treatment of Generalized Anxiety Disorder in the second quarter of 2006 and a Phase 2 clinical trial for the treatment of insomnia in the fourth quarter of 2007;

- MN-221 for the treatment of preterm labor, for which we completed a Phase 1 clinical trial to investigate the pharmacokinetic profile of MN-221 in healthy pregnant women not in labor in the second quarter of 2007;

MN-246 for the treatment of urinary incontinence, for which we completed a Phase 1 clinical trial in the fourth quarter of 2006 and a Phase 1 food effects study in the first quarter of 2007;

MN-447 for the treatment of thrombotic disorders, which remains in preclinical development; and

MN-462 for the treatment of thrombotic disorders, which remains in preclinical development.

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Avigen Transaction

In December 2009, Absolute Merger, Inc., a wholly-owned subsidiary of ours, merged with and into Avigen, with Avigen continuing as the surviving entity and wholly-owned subsidiary of ours. Under the terms of the merger, we issued $29.4 million in secured convertible notes that mature on June 18, 2011, the 18-month anniversary of the closing of the merger. Holders of these convertible notes may convert their notes into our common stock at an initial conversion price of $6.80 per share. At the maturity of the convertible notes, the remaining holders would be paid out the same per share amount as the Avigen shareholders that elected to receive cash at the merger closing, plus accrued interest. As part of the merger consideration, the former Avigen shareholders were also entitled to receive approximately $0.04 per share, which was paid in two increments in 2010, and rights under contingent payment rights issued as part of the merger consideration.

As a result of the Avigen transaction, our consolidated financial statements include Avigen s operations after the completion of the acquisition. We accounted for the Avigen merger using the acquisition method of accounting. As a result, we recorded $4.8 million of IPR&D related to Avigen s AV411 asset and we recorded $9.6 million of goodwill related to the excess purchase price over the assigned values of the net assets acquired. The goodwill was primarily a result of the conversion feature related to the convertible notes issued pursuant to the merger agreement. Our annual test date for IPR&D and goodwill impairment is December 31. We operate as one reporting segment and during the three months ended March 31, 2011 through the date of this report, there were no triggering events, market conditions (such as a drop in our stock price by more than 50%) or other factors (such as adverse clinical trial results) that would indicate possible or actual impairment of IPR&D or goodwill.

Debt

On May 10, 2010, we entered into a loan and security agreement, or the Loan Agreement, with Oxford, under which we borrowed $15.0 million. The financing is used to satisfy working capital needs, including the continued clinical development of MN-221. The stated interest rate on the loan was 12.87 percent. The effective interest rate on the loan was 18.14 percent when taking into consideration the deferred interest payment, the relative fair value of the warrants issued in connection with the loan and the fees associated with procuring the loan. Pursuant to the Loan Agreement, we also issued to Oxford a warrant to acquire up to 198,020 shares of our common stock, par value $0.001 per share, at an exercise price of $6.06 per share. Based on a Black Scholes model, the relative fair value of the warrant was approximately $859,000. In addition, the warrant and debt instrument are immediately separable and were issued separately; thus, we accounted for the warrant as a component of stockholders equity as the agreement requires settlement in shares and under no provision of the agreement are we required to settle the warrant in cash.

We accounted for the interest on the debt under the effective interest method wherein we treated the debt issuance costs paid directly to Oxford and the fair value of the warrants issued to Oxford as a discount on the debt (or a contra liability) and we treated the debt issuance costs paid to third parties as an asset. The related amortization of the debt discount is recorded as interest expense and the amortization of the debt issuance costs paid to third parties is recorded as other expense in our consolidated statement of operations.

On March 31, 2011, we and Oxford executed a pay-off letter in which Oxford waived early payment penalties of approximately $437,000 and we repaid the loan in full on April 1, 2011.

Reduction-in-Force

In January 2011, we commenced a reduction-in-force, or RIF, wherein we down-sized the company to save costs. We believe that with this RIF, we are adequately staffed given our research and development focus and that we are a development stage company.

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Chinese Joint Venture

On March 3, 2011, we executed a joint venture letter of intent with Zhejiang Medicine Co., Ltd. and Beijing Make-Friend Medicine Technology Co., Ltd., which provides for the establishment of a joint venture company to develop and commercialize MN-221 in China. As of the date of the filing of this Quarterly Report on Form 10-Q, we have not yet completed the joint venture contract or applicable licensing agreement.

Underwritten Firm Commitment Public Offering

On March 23, 2011, we announced a firm-commitment underwritten public offering of 2,750,000 units at a price to the public of $3.00 per unit for gross proceeds of $8.25 million. Each unit consists of one share of common stock, and a warrant to purchase one share of common stock. The shares of common stock and warrants are immediately separable and were issued separately. The warrants are exercisable immediately upon issuance, have a five-year term and an exercise price of $3.56 per share. On March 24, 2011, the underwriter exercised 50,666 units of its 412,500 unit overallotment. On March 29, 2011, we received net proceeds of approximately $7.9 million, after underwriter discount and underwriter expenses and no warrants exercised. In accordance with the authoritative guidance, we concluded that the warrants were indexed to our stock and do not permit net-cash settlement. Therefore, the warrants were classified as equity instruments and are not being marked to market prospectively as long as they continue to meet the conditions for equity classification.

Revenues and Cost of Revenues

We have not generated any revenues from licensing, milestones or product sales to date, and we do not expect to generate any revenues from the commercialization of our product candidates within the next several years, if at all. Our revenues to date have been generated from providing development management services under master service agreements with Asahi Kasei Pharma Corporation and Argenes, Inc., pursuant to which we billed consulting fees and our pass-through clinical contract costs. The primary costs associated with our revenue were the clinical contract costs we incurred and passed-through to our customers. Our agreement with Asahi Kasei Pharma Corporation has been completed, and we terminated our agreement with Argenes, Inc. Therefore, we will not generate any further revenue from these agreements.

Research and Development

Our research and development expenses consist primarily of the license fees related to our product candidates, salaries and related employee benefits, costs associated with the preclinical and clinical development of our product candidates, costs associated with non-clinical activities, such as regulatory expenses, and pre-commercialization manufacturing development activities. We use external service providers to manufacture our product candidates to be used in clinical trials and for the majority of the services performed in connection with the preclinical and clinical development of our product candidates; therefore, these research and development expenses consist substantially of external costs, such as fees paid to consultants, contract research organizations, contract manufacturers and other external service providers, including professional fees and costs associated with legal services, patents and patent applications for our intellectual property. Internal research and development expenses consist of costs of compensation and other expenses for research and development personnel, supplies, materials, facility costs and depreciation. Research and development costs are expensed as incurred or accrued based on certain contractual factors such as for estimates of work performed, milestones achieved, patient enrollment and experience with similar contracts. As actual costs become known, accruals are adjusted. To date, our estimates have not differed significantly from the actual costs incurred.

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The following table summarizes our research and development expenses for the periods indicated for each of our product candidates. To the extent that costs, including personnel costs, are not tracked to a specific product development program, such costs are included in the Unallocated category (in thousands):

Product Candidate	Disease/Indication	Three months ended March 31, 2011	2010
MN-221	Acute exacerbations of asthma/COPD	$ 1,945	$ 2,334
MN-166/AV411	Multiple sclerosis/other CNS disorders	152	261
MN-001	Bronchial asthma	5	13
MN-001	Interstitial cystitis	5	7
MN-029	Solid tumors	16	22
MN-305	Generalized Anxiety Disorder/insomnia		3
MN-221	Preterm labor	2	2
MN-246	Urinary incontinence	1	1
MN-447	Thrombotic disorders	7	
MN-462	Thrombotic disorders		
Unallocated		491	306
Total research and development		$ 2,624	$ 2,949

As of the end of the second quarter of 2007, we determined to focus our resources on the development of our two prioritized product candidates, MN-221 for the treatment of acute exacerbations of asthma and MN-166 for the treatment of MS. In the third quarter of 2009, we determined to expand the product development program for MN-221 to evaluate MN-221 for the treatment of COPD exacerbations. In the second quarter of 2008 we completed the Phase 2 clinical trial of MN-166 ibudilast for the treatment of MS and in December 2009, through the Avigen acquisition, we acquired AV411 ibudilast for the treatment of other CNS disorders. We continue to work on combing the two ibudilast-based development programs and we are pursuing discussions with potential partners to secure a strategic collaboration. As such, we do not plan to undertake any further significant clinical development of MN-166/AV411 until such time that we secure a strategic collaboration to advance the combined ibudilast-based development program. We anticipate that our research and development expenses will increase with respect to MN-221 over the next two quarters as we strive to complete the current clinical trial, MN-221 CL-007, which is set in the ER. In addition, with respect to MN-166/AV411, in future periods, we will limit expenditures on this product candidate to those development activities deemed necessary, if any, to maximize its value for purposes of securing a partner for clinical development.

Following the last protocol amendment change to MN-221-CL-007 in 2010, we are experiencing a higher average enrollment rate for the quarter over last year s average enrollment rate. While we anticipate enrolling the last patient in this study in the second half of 2011, due to the risks inherent in the clinical development process and given that this study is set in the ER, we are unable to estimate with certainty the costs that we will incur in the continued development of such product candidate and that we will complete this study as expected.

We will continue to limit our expenditures on the remainder of our existing product candidates to only those activities deemed necessary to maintain our license rights or maximize the value of such product candidates, if any, while pursuing a variety of initiatives to monetize such product candidates on appropriate terms. As a result, we expect that research and development expenses will decrease or otherwise remain low for the remainder of our existing product candidates in future periods.

General and Administrative

Our general and administrative expenses primarily consist of salaries, benefits and consulting and professional fees related to our administrative, finance, human resources, business development, legal and information systems support functions. In addition, general and administrative expenses include facilities and

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insurance costs. General and administrative costs are expensed as incurred or accrued based on monitoring the status of the specified project, contractual factors such as milestones or retainer fees, services provided and invoices received. As actual costs become known to us, we adjust our accruals. To date, general and administrative accruals have not differed significantly from the actual costs incurred.

We anticipate that our general and administrative expenses may increase in future periods if we are required to expand our infrastructure based on the success of our current prioritized product development programs and in raising capital to support those and other development programs or otherwise in connection with increased business development activities related to partnering, out-licensing or disposition of our product candidates.

Investment Securities and ARS Put

Our investment securities had consisted of auction rate securities, or ARS, all of which had AAA ratings at the time of original purchase. ARS are generally long-term debt instruments that historically have provided liquidity through a Dutch auction process that resets the applicable interest rate at predetermined calendar intervals, typically seven, 28, 35 or 49 days. All of our ARS principally represent insurance notes and portfolios of securities (primarily commercial paper).

Certain of our ARS were subject to a settlement in which we received the right to sell back certain of our ARS at par value at any time during the period beginning June 30, 2010 and ending July 2, 2012 and we were offered a no net cost loan program, or ARS Loan, whereby the interest cost would not exceed the interest being paid on the underlying ARS investments.

On December 31, 2008, we designated our investment securities portfolio as trading investment securities; therefore, any additional increase or decrease in the fair value of our investment securities is recorded as either a gain or an impairment charge, respectively, in our consolidated statement of operations. Investment security fair value determinations were made on a Level 3 basis utilizing a discounted cash flow model, employing liquidity discounts.

As of December 31, 2010, we no longer held any investment securities.

Foreign Exchange Loss/(Gain)

To date, we have conducted most of our clinical trials in the United States. However, the Phase 2 clinical trial for MN-166 for the treatment of MS that completed in 2008 was conducted in Eastern Europe and the on-going Phase 2 clinical trial in MN-221 for the treatment of acute exacerbations of asthma, had a few clinical sites located in Australia and New Zealand in which certain of the invoices were denominated the Australian dollar and New Zealand dollar, respectively. In addition, we have certain investor relation invoices denominated in Japanese Yen and we have certain manufacturing invoices denominated in British Pound. At this time, we have not established a hedging program to mitigate our foreign exchange exposure. Foreign exchange gain/loss is based on the difference between the exchange rate at the settlement date and the exchange rate at the balance sheet date for the respective foreign currency invoice.

Other Expense

Other expense consists of accretion related to the convertible notes and the amortization of debt issuance costs paid to third parties.

Interest Expense

Interest expense consists of interest charged on our ARS Loan, interest charged on our long-term debt based on the effective interest method and amortization of debt discount.

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Other Income

Other income consists of interest earned on our cash, cash equivalents and investment securities.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of the consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the related disclosure of contingent liabilities. We review our estimates on an ongoing basis, including those related to our significant accruals. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions. Our critical accounting policies and estimates are the same as those noted in our Annual Report on Form 10-K for the year ended December 31, 2010, as filed with the SEC on March 31, 2011.

New Accounting Pronouncements

In December 2010, the Financial Accounting Standards Board, or FASB, issued updated guidance related goodwill impairment testing. The guidance requires an entity to use an equity premise when performing the first step of a goodwill impairment test and if a reporting unit has a zero or negative carrying amount, the entity must assess and consider qualitative factors and whether it is more likely than not that a goodwill impairment exists. The second step continues to compare the carrying amount of the reporting unit s goodwill to its implied fair value. The guidance is effective for public entities, for impairment tests performed during entities fiscal years (and interim periods within those years) that begin after December 15, 2010. We early adopted the updated guidance in January 2011 and using the transitional approach we determined not to perform an interim goodwill impairment test given that we operate as one reporting segment and did not have a zero or negative carrying amount. We will continue to monitor our stock price and equity and assess qualitative factors. However, should our stock price continue to decline, possible impairment of goodwill could have a material impact on our consolidated financial statements.

In December 2010, FASB clarified guidance related to business combinations. Public entities involved in a business combination are now required to disclose revenue and earnings of the combined entity as though the combination that occurred during the current year had occurred as of the beginning of the comparable prior period being presented. It also requires that supplemental pro forma disclosures include a description of the nature and amount of material, nonrecurring pro forma adjustments directly attributable to the business combination be included. This guidance is effective for us for acquisitions occurring on or after the beginning of our 2011 fiscal year. This will not have an effect on our condensed consolidated financial statements.

Results of Operations

Comparison of the Three Months Ended March 31, 2011 and 2010

Revenues

There were no revenues for the three months ended March 31, 2011 or March 31, 2010.

Research and Development

Research and development expenses for the three months ended March 31, 2011 were $2.6 million, a decrease of $0.3 million when compared to $2.9 million for the three months ended March 31, 2010. This decrease in research and development expenses was due to a decrease of $0.4 million in spending on our

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prioritized asset MN-221 for the treatment of acute exacerbations of asthma and COPD primarily due to the completion of the COPD clinical trial in 2010 and a decrease of $0.1 million in spending on our prioritized asset MN-166/AV411, primarily due to the completion of the monkey toxicity preclinical work completed in 2010, offset by an increase of $0.2 million in unallocated research and development expenses due to the payout of accrued vacation and severance in connection with the reduction-in-force that occurred in January 2011.

General and Administrative

General and administrative expenses were $2.4 million for the three months ended March 31, 2011, an increase of $0.1 million when compared to $2.3 million for the three months ended March 31, 2010. This increase in general and administrative expenses was primarily due to an increase of $0.4 million related to employee termination benefits paid out in the first quarter of 2011, offset by a reduction in stock based compensation expenses of $0.3 million due to employee terminations and fully amortized options.

Impairment Charge/Gain, net, on Investment Securities

Impairment charge/gain on investment securities for the three months ended March 31, 2011 was $0, as compared to a net impairment charge on investment securities of $7,000 for the three months ended March 31, 2010. In 2011 we no longer held any investment securities.

Foreign Exchange Loss/Gain

Foreign exchange gain for the three months ended March 31, 2011 was $400, as compared to a foreign exchange loss of $4,000 for the three months ended March 31, 2010. The foreign exchange gain/loss for the three months ended March 31, 2011 and 2010 relate to the remeasurement of foreign payables.

Other Expense

Other expense for the three months ended March 31, 2011 was $53,000, as compared to $31,000 for the three months ended March 31, 2010. Other expense relates to accretion on the convertible notes and amortization of debt issuance costs paid to third parties. We did not have debt in the first quarter of 2010.

Interest Expense

Interest expense for the three months ended March 31, 2011 was $652,000, as compared to $44,000 for the three months ended March 31, 2010. The increase in interest expense was due to the interest charged on the debt using the effective interest method, offset by a decrease in the amount of interest charged on the ARS Loan. We did not have debt in the first quarter of 2010 and the ARS Loan was repaid in the third quarter of 2010.

Other Income

Other income for the three months ended March 31, 2011 was $25,000, as compared to $161,000 for the three months ended March 31, 2010. The decrease is due to a decrease in interest income due to a lower yield earned on invested balances as we converted higher yielding investment securities into cash and cash equivalents subsequent to March 2010, which were invested in money market funds to preserve liquidity and principal.

Liquidity and Capital Resources

We incurred losses of $5,655,730 for the three months ended March 31, 2011 and we have incurred losses of $20,187,308, $20,368,890 and $21,924,829 for the years ended December 31, 2010, 2009, and 2008 respectively. We have an accumulated deficit of $273,194,136 as of March 31, 2011. Additionally, we have used net cash of $3,963,017, $17,698,079, $17,014,162 and $21,118,380 to fund our operating activities for the three

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months ended March 31, 2011 and for the years ended December 31, 2010, 2009, and 2008, respectively. To date these operating losses have been funded primarily through the private placement of our equity securities, the public sale of our common stock, long-term debt, the conversion of convertible notes to our common stock and the exercise of founders warrants, net of treasury stock repurchases.

As a development stage company, we have consumed substantial amounts of capital since our inception. We do not have any material commitments for capital expenditures; however, we have an on-going 200 patient Phase 2 clinical trial (MN-221-CL-007) for which we expect to complete enrollment in the second half of 2011. Our clinical studies are administered by third-party CROs and there is a significant degree of estimation involved in quantifying the expense associated with clinical trial activity. We accrue costs for work performed by CROs based on the achievement of contracted milestone activities and on internal estimates of activities using patient enrollment and contractual or estimated rates during the period. If we do not receive complete and accurate information from the CRO or third parties on a timely basis or correctly estimate the outcome of contract negotiations, activity levels and the enrollment rate, this could potentially impact R&D expense and cash payments in subsequent periods.

We have had, and continue to have, an ongoing need to raise additional cash from outside sources to fund our operations. We have an established history of raising capital through equity and debt, and we are currently involved in discussions with multiple parties. In March 2011, we raised approximately $7.9 million in net proceeds from a firm underwritten public offering in which we offered 2,750,000 units, with each unit consisting of one share of common stock and a warrant to purchase one share of common stock. The purchase price for each unit was $3.00 and each warrant has an exercise price of $3.56 per share. In addition, in March 2011, the underwriter exercised 50,666 units of its 412,500 unit overallotment. Our current cash and cash equivalents, along with the proceeds from this offering, are our principal sources of liquidity as we cannot be assured of future conversion of the convertible notes into our common stock. Our business will continue to require us to incur substantial research and development. We also have assumed that all of our restricted cash will be used to pay our convertible notes that mature on June 18, 2011, although one or more holders may elect to convert some or all of the convertible notes to common stock at a conversion rate of $6.80 per share prior to the maturity date.

Although there can be no assurance given, we hope to successfully complete one or more additional financing transactions and/or corporate partnerships in the near-term; otherwise, we will not have sufficient cash or other liquidity to fund our operations as currently conducted and staffed for the following 12 months which raises substantial doubt as to our ability to continue as a going concern. The accompanying consolidated financial statements have been prepared assuming that we will continue as a going concern. If we are unsuccessful in our efforts to raise outside capital in the immediate near term through our effective S-3 shelf registration and/or our discussions with potential strategic partners, we will be required to delay, reduce the scope of or terminate one or more of our product development programs and relinquish some or even all rights to product candidates. In parallel, we would be required to implement another RIF, implement additional cost reduction measures related to compensation and employee benefits, and reduce our professional fees and our travel spending to minimize operating costs, to offset the lack of available funding.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Our primary exposure to market risk due to changes in interest rates relates primarily to the increase or decrease in the amount of interest income we can earn on our investment portfolio. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive without significantly increasing risk. Our risk associated with fluctuating interest rates is limited to our investments in interest rate sensitive financial instruments. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We mitigate default risk by investing in investment grade securities. A hypothetical 100 basis point adverse move in interest rates along the entire interest rate yield curve would not materially affect the fair value of our interest sensitive financial instruments due to their relatively short term nature. Declines in interest rates over time, however, will reduce our interest income, while increases in interest rates over time will increase our interest income.

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Cash and cash equivalents as of March 31, 2011 were $31.4 million and were primarily invested in money market interest bearing accounts and money market funds. A hypothetical 10% adverse change in the average interest rate on our money market cash investments and short-term investments would have had no material effect on net income for the year ended March 31, 2011.

ITEM 4. CONTROLS AND PROCEDURES.

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports pursuant to the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(b) of the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the quarter covered by this report. Based on the foregoing, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

On March 3, 2011, we received a legal letter from a former employee who had been terminated in January 2011 pursuant to our planned reduction-in-force to save costs. The legal letter did not assert a claim outright; however, there were allegations made in the legal letter that could threaten litigation against us. We have engaged legal counsel in connection with the possibility of a lawsuit given this legal letter and the fact that this former employee s separation agreement has expired. Given the inherent uncertainty and unpredictability of litigation and due to the status of this legal action, no range of loss or possible loss can be reasonably estimated. However, we do not expect the outcome of this matter to have a material adverse effect on our consolidated financial statements.

We may become involved in various disputes and legal proceedings which arise in the ordinary course of business. While it is not possible to accurately predict or determine the outcome of these matters, an adverse result in any of these matters may occur which could harm our business.

ITEM 1A. RISK FACTORS.

We operate in a dynamic and rapidly changing environment that involves numerous risks and uncertainties. Certain factors may have a material adverse effect on our business, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in this Quarterly Report on Form 10-Q and our other public filings with the SEC. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our results of operations and financial condition.

Risks Related to Our Business and Industry

We have incurred significant operating losses since our inception and expect that we will incur continued losses for the foreseeable future.

We are a development stage biopharmaceutical company with a limited operating history. We have incurred significant net losses since our inception. For the three months ended March 31, 2011, we had a net loss of $5.7 million and our accumulated deficit was approximately $273.2 million. If we are successful in securing a strategic collaboration or in raising additional capital to support the expansion of our business, our annual net losses may increase over the next several years as we expand our infrastructure and incur significant costs related to the development of our product candidates.

If we have taxable income in the future, utilization of the net operating losses, or NOL, and tax credit carryforwards will be subject to a substantial annual limitation under Section 382 and 383 of the Internal Revenue Code of 1986, and similar state provisions due to ownership change limitations that have occurred. These ownership changes will limit the amount of NOL and tax credit carryforwards that can be utilized to offset future taxable income and tax, respectively.

We believe our existing cash and cash equivalents at March 31, 2011 will be sufficient to fund our debt repayment obligations, our forecasted research and development expenses and our fixed obligations over the next 12 months. However, we will need to successfully complete one or more additional financing transactions and/or corporate partnerships in the near-term; otherwise, we will not have sufficient cash or other liquidity to fund our operations as currently conducted and staffed for the following 12 months which raises doubt as to our ability to continue as a going concern.

These assumptions may prove to be wrong, and we could spend our available financial resources before we complete the clinical trial. Our future capital requirements will also depend on many factors, including:

- progress in, and the costs of, future planned clinical trials and other research and development activities;

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- the scope, prioritization and number of our product development programs;
- our obligations under our license agreements, pursuant to which we may be required to make future milestone payments upon the achievement of various milestones related to clinical, regulatory or commercial events;
- our ability to establish and maintain strategic collaborations, including licensing and other arrangements, and to complete acquisitions of additional product candidates;
- the time and costs involved in obtaining regulatory approvals;
- the costs of securing manufacturing arrangements for clinical or commercial production of our product candidates;
- the costs associated with expanding our management, personnel, systems and facilities;
- the costs associated with any litigation;
- the costs associated with the operations or wind-down of any business we may acquire;
- the costs involved in filing, prosecuting, enforcing and defending patent claims and other intellectual property rights; and
- the costs of establishing or contracting for sales and marketing capabilities and commercialization activities if we obtain regulatory approval to market our product candidates.

We expect our research and development expenses to increase in connection with ongoing and planned clinical trials primarily related to MN-221 for the treatment of acute exacerbations of asthma and COPD exacerbations, and any other development activities that it may initiate. In addition, our general and administrative expenses may increase in future periods as a result of several factors, including our research and development activities, our business development activities and any expansions in our infrastructure related to such activities. Consequently, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing drug products, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

If we fail to obtain the capital necessary to fund our operations, we will be unable to develop and commercialize our product candidates.

We have consumed substantial amounts of capital since our inception. From our inception to March 31, 2011, we had an accumulated deficit of $273.2 million. Our cash and cash equivalents were approximately $31.4 million at March 31, 2011.

Our business will continue to require us to incur substantial research and development expenses and we do not expect to be able to fund these expenses solely from upfront cash or milestones from collaborations or strategic alliances. As such we may be required to raise capital from one or more sources in the near term to continue our operations at or close to the levels currently conducted. We believe that without raising additional capital soon from accessible sources of financings, we will not otherwise have adequate funding to complete the development of MN-221 including pivotal clinical trials or the commercialization of any products we successfully develop. We have assumed that all of our restricted cash will be used to pay our convertible notes that mature on June 18, 2011, although one or more holders may elect to convert some or all of the convertible notes to common stock at a conversion rate of $6.80 per share prior to the maturity date. There is no guarantee that adequate funds will be available when needed from additional debt or equity financing, arrangements with partners, or from other sources, or on terms attractive to us. The inability to obtain sufficient additional funds when needed to fund our operations would require us to significantly delay, scale back, or eliminate some or all of our clinical or regulatory activities, further reduce general and administrative expenses and have a substantial negative effect on our results of operations and financial condition.

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We do not have any products that are approved for commercial sale and therefore do not expect to generate any revenues from product sales in the foreseeable future, if ever.

To date, we have funded our operations primarily from sales of our securities and, to a lesser extent, debt financing. We have not received, and do not expect to receive for at least the next several years, if at all, any revenues from the commercialization of our product candidates. Our only source of revenues since inception has been from development management services rendered to Asahi Kasei Pharma Corporation and Argenes, Inc., both Japanese pharmaceutical companies, in connection with their clinical development of pharmaceutical product candidates. We completed our agreement with Asahi Kasei Pharma Corporation and terminated our agreement with Argenes, Inc.; therefore, we will not generate any further revenues from these agreements. We anticipate that, prior to our commercialization of a product candidate, out-licensing upfront and milestone payments will be our primary source of revenue if we can enter into collaborations, strategic alliances or other agreements that would provide us with such revenues. To obtain revenues from sales of our product candidates, we must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, manufacturing and marketing drugs with commercial potential. We may never succeed in these activities, and we may not generate sufficient revenues to continue our business operations or achieve and maintain profitability.

We are largely dependent on the success of our two prioritized product candidates, MN-221 and MN-166/AV411, and we cannot be certain that either of these product candidates will receive regulatory approval or be successfully commercialized.

We currently have no products for sale, and we cannot guarantee that we will ever have any drug products approved for sale. The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the FDA and comparable regulatory authorities in other countries. We are not permitted to market any of our product candidates in the United States until we submit and receive approval of a New Drug Application, or NDA, for a product candidate from the FDA or its foreign equivalent from a foreign regulatory authority. Obtaining FDA approval is a lengthy, expensive and uncertain process. We currently have two prioritized product candidates, MN-221 for the treatment of acute exacerbations of asthma and COPD exacerbations and MN-166/AV411, a combined ibudilast product development program covering MS and other CNS disorders, and the success of our business currently depends on their successful development and commercialization. Neither of these product candidates has completed the clinical development process; therefore, we have not submitted an NDA or foreign equivalent or received marketing approval for either of these two prioritized product candidates. In addition, we are not currently planning to fund any further significant clinical development of MN-166/AV411 until such time that we are able to secure a strategic collaboration to advance the combined development programs, which may delay or impede the process of completing clinical trials and seeking regulatory approval for this product candidate. We also cannot assure you that we will be able to secure such a strategic collaboration on attractive financial and other terms, or at all.

The clinical development programs for MN-221 and MN-166/AV411 may not lead to commercial products for a number of reasons, including our clinical trials failure to demonstrate to the FDA s satisfaction that these product candidates are safe and effective or our failure to obtain necessary approvals from the FDA or similar foreign regulatory authorities for any reason. We may also fail to obtain the necessary approvals if we have inadequate financial or other resources to advance our product candidates through the clinical trial process or are unable to secure a strategic collaboration or partnership with a third party. Any failure or delay in completing clinical trials or obtaining regulatory approval for either MN-221 or MN-166/AV411 in a timely manner would have a material and adverse impact on our business and our stock price.

In order to commercialize a therapeutic drug successfully, a product candidate must receive regulatory approval after the successful completion of clinical trials, which are long, complex and costly, have a high risk of failure and can be delayed or terminated at any time.

Our product candidates are subject to extensive government regulations related to development, clinical trials, manufacturing and commercialization. The process of obtaining FDA and other regulatory approvals is

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costly, time-consuming, uncertain and subject to unanticipated delays. To receive regulatory approval for the commercial sale of any of our product candidates, we must conduct, at our own expense, adequate and well-controlled clinical trials in human patients to demonstrate the efficacy and safety of the product candidate. Clinical testing is expensive, takes many years and has an uncertain outcome. To date, we have obtained regulatory authorization to conduct clinical trials for eight of our product development programs. Investigational New Drug Applications, or INDs, were approved by the FDA and are active for seven of our product candidates. We also have obtained Clinical Trial Authorizations, or CTAs, for the ongoing Phase 2 clinical trial for MN-221 in Canada, Australia and New Zealand. Through the acquisition of Avigen, we have assumed responsibility for AV411 clinical trials including one active IND for neuropathic pain and cross-reference and drug product support of the NIDA-funded opioid withdrawal investigator-initiated IND with Columbia University drug addiction clinical researchers. In the third quarter of 2010, a NIDA-funded investigator-initiated IND with University of California Los Angeles was given approval by the FDA to proceed with an initial trial of our neurological drug candidate, ibudilast (MN-166/AV411), as a potential new pharmacotherapy for methamphetamine addiction. The study will be led by established clinical research investigators in the treatment of drug addiction.

It may take years to complete the clinical development necessary to commercialize a drug, and delays or failure can occur at any stage, which may result in our inability to market and sell any products derived from any of our product candidates that are ultimately approved by the FDA or foreign regulatory authorities. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or non-clinical testing. For example, in October 2007, we announced that our Phase 2 clinical trial of MN-305 for the treatment of insomnia failed to achieve statistical significance in its primary endpoint, and, as a result, we terminated development of MN-305 for the treatment of insomnia. Of the large number of drugs in development, only a small percentage result in the submission of an NDA to the FDA and even fewer are approved for commercialization. Interim results of clinical trials do not necessarily predict final results, and success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials even after promising results in earlier clinical trials. In addition, any delays in completing clinical trials or the rejection of data from a clinical trial by a regulatory authority will result in increased development costs and could have a material adverse effect on the development of the impacted product candidate.

In connection with the conduct of clinical trials for each of our product candidates, we face many risks, including the risks that:

- the product candidate may not prove to be effective in treating the targeted indication;
- patients may die or suffer other adverse effects for reasons that may or may not be related to the product candidate being tested;
- the results may not confirm the positive results of earlier trials;
- the FDA or other regulatory authorities may not agree with our proposed development plans or accept the results of completed clinical trials; and
- our planned clinical trials and the data collected from such clinical trials may be deemed by the FDA or other regulatory authorities not to be sufficient, which would require additional development for the product candidate before it can be evaluated in late stage clinical trials or before the FDA will consider an application for marketing approval.

If we do not complete clinical development of our product candidates successfully, we will be unable to obtain regulatory approval to market products and generate revenues from such product candidates. We may also fail to obtain the necessary regulatory approvals if we have inadequate financial or other resources to advance our product candidates through the clinical trial process. In addition, even if we believe that the preclinical and clinical data are sufficient to support regulatory approval for a product candidate, the FDA and foreign regulatory authorities may not ultimately approve such product candidate for commercial sale in any jurisdiction, which

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would limit our ability to generate revenues and adversely affect our business. In addition, even if our product candidates receive regulatory approval, they remain subject to ongoing FDA regulations, including obligations to conduct additional clinical trials, changes to the product label, new or revised regulatory requirements for manufacturing practices, written advisements to physicians, and/or a product recall or withdrawal.

Delays in the commencement or completion of clinical trials, or suspension or termination of our clinical trials, could result in increased costs to us and delay or limit our ability to obtain regulatory approval for our product candidates.

If we experience delays in the commencement or completion of our clinical trials, we could incur significantly higher product development costs and our ability to obtain regulatory approvals for our product candidates could be delayed or limited. The commencement and completion of clinical trials requires us to identify and maintain a sufficient number of study sites and enroll a sufficient number of patients at such sites. We do not know whether enrollment in our ongoing and planned clinical trials for our product candidates will be completed on time, or whether our additional planned and ongoing clinical trials for our product candidates will be completed on schedule, if at all. For example, through the third quarter of 2010 we continued to experience an overall slower than anticipated enrollment of patients for our ongoing Phase 2 clinical trial evaluating the safety and efficacy of MN-221 in patients with severe, acute exacerbations of asthma for various reasons such as the length of time required to stay in the emergency room, or ER, during the treatment period. Our enrollment rates have improved since September 30, 2010, we believe, due in part to changes to the protocol that shortened the length of time the patient needed to stay in the ER and that gave the ER physician control over the standard-of-care that was given to the patient during the treatment period. However, there is no assurance that we will complete enrollment in the second half of 2011.

The commencement and completion of clinical trials can be delayed for a variety of other reasons, including delays in:

- obtaining regulatory approval to commence or amend a clinical trial;
- reaching agreements on acceptable terms with prospective clinical research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- recruiting and enrolling patients to participate in clinical trials;
- retaining patients who have initiated a clinical trial but who may be prone to withdraw due to the treatment protocol, lack of efficacy, personal issues or side effects from the therapy or who are lost to further follow-up;
- manufacturing sufficient quantities of a product candidate; and
- IRB approval or approval from foreign counterparts to conduct or amend a clinical trial at a prospective site.

In addition, a clinical trial may be delayed, suspended or terminated by us, the FDA or other regulatory authorities due to a number of factors, including:

- ongoing discussions with regulatory authorities regarding the scope or design of our clinical trials or requests by them for supplemental information with respect to our clinical trial results, which may result in the imposition of a clinical hold on the IND for any clinical trial, as well as the inability to resolve any outstanding concerns with the FDA so that a clinical hold already placed on the IND may be lifted and the clinical trial may begin;

inspections of our own clinical trial operations, the operations of our CROs or our clinical trial sites by the FDA or other regulatory authorities, which may result in the imposition of a clinical hold or potentially prevent us from using some of the data generated from our clinical trials to support requests for regulatory approval of our product candidates;

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- our failure or inability, or the failure or inability of our CROs, clinical trial site staff or other third party service providers involved in the clinical trial, to conduct clinical trials in accordance with regulatory requirements or our clinical protocols;

- lower than anticipated enrollment or retention rates of patients in clinical trials;

- new information suggesting unacceptable risk to subjects or unforeseen safety issues or any determination that a trial presents unacceptable health risks;

- insufficient supply or deficient quality of product candidates or other materials necessary for the conduct of our clinical trials; and

- lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our CROs and other third parties.

If we experience delays in the completion of our clinical trials for a product candidate, the commercial prospects for such product candidate may be harmed, we may incur increased costs for development of such product candidate and our ability to obtain regulatory approval for such product candidate could be delayed or limited. Many of the factors that cause or lead to delays in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval for a product candidate. In addition, any amendment to a clinical trial protocol may require us to resubmit our clinical trial protocols to IRBs or their foreign counterparts for reexamination, which may delay or otherwise impact the costs, timing or successful completion of a clinical trial.

The loss of any rights to develop and market any of our product candidates could significantly harm our business.

With the exception of AV411, we license the rights to develop and market our product candidates. Currently, we have licensed rights relating to eight compounds for the development of ten product candidates.

We are obligated to develop and commercialize these product candidates in accordance with mutually agreed upon terms and conditions. Our ability to satisfy some or all of the terms and conditions of our license agreements is dependent on numerous factors, including some factors that are outside of our control. Any of our license agreements may be terminated if we breach our obligations under the agreement materially and fail to cure any such breach within a specified period of time.

If any of our license agreements is terminated, we would have no further rights to develop and commercialize the product candidate that is the subject of the license. The termination of the license agreements related to either of our two prioritized product candidates would significantly and adversely affect our business. The termination of any of the remainder of our license agreements could materially and adversely affect our business.

If our competitors develop and market products that are more effective than our product candidates, they may reduce or eliminate our commercial opportunities.

The biotechnology and pharmaceutical industries are subject to rapid and intense technological change. We face, and will continue to face, competition from pharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies, in the United States and abroad. Some of these competitors have products or are pursuing the development of drugs that target the same diseases and conditions that are the focus of our product development programs. We cannot assure you that developments by others will not render our product candidates obsolete or noncompetitive. Many of our competitors have products that have been approved or are in advanced development and may succeed in developing drugs that are more effective, safer, more affordable or more easily administered than ours, or that achieve patent protection or

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commercialization sooner than our products. Our competitors may also develop alternative therapies that could further limit the market for any products that we are able to obtain approval for, if at all. In addition, new developments, including the development of other drug technologies and methods of preventing the incidence of disease, occur in the pharmaceutical industry at a rapid pace. These developments may render our product candidates obsolete or noncompetitive.

In many of our target disease areas, potential competitors are working to develop new compounds with different mechanisms of action and attractive efficacy and safety profiles. Many of our competitors have substantially greater financial, research and development resources, including personnel and technology, clinical trial experience, manufacturing, sales and marketing capabilities and production facilities than we do. Smaller companies also may prove to be significant competitors, particularly through proprietary research discoveries and collaboration arrangements with large pharmaceutical and established biotechnology companies.

Our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective and less costly than ours and may also be more successful than us in manufacturing and marketing their products. We also expect to face similar competition in our efforts to identify appropriate collaborators or partners to help develop or commercialize our product candidates.

We will depend on strategic collaborations with third parties to develop and commercialize selected product candidates and will not have control over a number of key elements relating to the development and commercialization of these product candidates if we are able to achieve such third-party arrangements.

A key aspect of our strategy is to seek collaborations with partners, such as large pharmaceutical companies, that are willing to conduct later-stage clinical trials and further develop and commercialize selected product candidates. Following completion of the Phase 2 clinical trial for MN-166 for the treatment of MS in the second quarter of 2008 and the acquisition of AV411 in December 2009, we do not plan to undertake any further significant clinical development activities for any of our product candidates other than MN-221 for the treatment of acute exacerbations of asthma and COPD exacerbations, other than those activities deemed necessary to maximize each product candidate s value, until such time that we are successful in entering into a partnership or collaboration to further development of such product candidates. To date, we have not entered into any such collaborative arrangements, and we may not be able to enter into any collaborations or otherwise monetize these product candidates on acceptable terms, if at all.

By entering into a strategic collaboration with a partner, we may rely on the partner for financial resources and for development, regulatory and commercialization expertise. Even if we are successful in entering into a strategic collaboration for one of our product candidates, our partner may fail to develop or effectively commercialize the product candidate because such partner:

- does not have sufficient resources or decides not to devote the necessary resources due to internal constraints such as limited cash or human resources;
- decides to pursue a competitive potential product developed outside of the collaboration;
- cannot obtain the necessary regulatory approvals;
- determines that the market opportunity is not attractive; or
- cannot manufacture the necessary materials in sufficient quantities from multiple sources or at a reasonable cost.

We also face competition in our search for partners from other biotechnology and pharmaceutical companies worldwide, many of whom are larger and able to offer more attractive deals in terms of financial commitments, contribution of human resources, or development, manufacturing, regulatory or commercial expertise and support.

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If we are not successful in attracting partners and entering into collaborations on acceptable terms for these product candidates or otherwise monetizing these product candidates, we may not be able to complete development of or obtain regulatory approval for such product candidates. In such event, our ability to generate revenues from such products and achieve or sustain profitability would be significantly hindered.

The terms under which we raise additional capital or debt financing may harm our business and may significantly dilute stockholders ownership interests.

If we raise additional funds through collaborations or licensing arrangements with third parties, we may need to relinquish some rights to our product candidates, including commercialization rights, which may hinder our ability to generate revenues and achieve or sustain profitability. If we raise additional funds by issuing equity securities, including as part of a debt financing, stockholders may experience substantial dilution. Debt financing, if available, may involve significant cash payment obligations and restrictive covenants and other financial terms that may impede our ability to operate our business. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders.

We are subject to stringent regulation of our product candidates, which could delay the development and commercialization of our product candidates.

We, our third-party manufacturers, service providers, suppliers and partners, and our product candidates are subject to stringent regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. None of our product candidates can be marketed in the United States until it has been approved by the FDA. None of our product candidates has been approved by the FDA to date, and we may never receive FDA approval for any of our product candidates. Obtaining FDA approval for a product takes many years of clinical development and requires substantial resources. Additionally, changes in regulatory requirements and guidance may occur or new information regarding the product candidate or the target indication may emerge, and we may need to perform additional, unanticipated non-clinical or clinical testing of our product candidates or amend clinical trial protocols to reflect these changes. Any additional unanticipated testing would add costs and could delay or result in the denial of regulatory approval for a product candidate. These regulatory requirements may limit the size of the market for the product or result in the incurrence of additional costs. Any delay or failure in obtaining required approvals could substantially reduce or negate our ability to generate revenues from the particular product candidate.

In addition, both before and after regulatory approval, we, our partners and our product candidates are subject to numerous FDA requirements, including requirements related to testing, manufacturing, quality control, labeling, advertising, promotion, distribution and export. The FDA s requirements may change and additional government regulations may be promulgated that could affect us, our partners and our product candidates. Given the number of recent high profile adverse safety events with certain drug products, the FDA may require, as a condition of approval, costly risk management programs, which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, preapproval of promotional materials and restrictions on direct-to-consumer advertising. Furthermore, we cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad.

In order to market any of our products outside of the United States, we and our strategic partners and licensees must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods beyond the requirements of the FDA and the time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the United States. Regulatory approval in one country, including FDA approval in the United States, does not ensure regulatory approval in another. In addition, a failure or delay in obtaining regulatory approval in one country may

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negatively impact the regulatory process in others. A product candidate may not be approved for all indications that we request, which would limit the uses of our product and adversely impact our potential royalties and product sales, and any approval that we receive may be subject to limitations on the indicated uses for which the product may be marketed or require costly, post-marketing follow-up studies.

If we fail to comply with applicable regulatory requirements in the United States or other countries, we may be subject to regulatory and other consequences, including fines and other civil penalties, delays in approving or failure to approve a product, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, interruption of manufacturing or clinical trials, injunctions and criminal prosecution, any of which would harm our business.

We rely on third parties to conduct our clinical trials, and we may incur additional development costs, experience delays in the commencement and completion of clinical trials, and be unable to obtain regulatory approval for or commercialize our product candidates on our anticipated timeline if these third parties do not successfully carry out their contractual duties or meet expected deadlines.

We rely extensively on CROs, medical institutions, clinical investigators, contract laboratories and other service providers to perform important functions related to the conduct of our clinical trials, the collection and analysis of data and the preparation of regulatory submissions. Although we design and manage our current clinical trials to ensure that each clinical trial is conducted in accordance with its investigational plan and protocol, we do not have the ability to conduct all aspects of our clinical trials directly for our product candidates.

The FDA requires us and our CROs to comply with regulations and standards, commonly referred to as good clinical practices, or GCPs, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. Our reliance on CROs does not relieve us of these responsibilities and requirements. The CROs, medical institutions, clinical investigators, contract laboratories and other service providers that we employ in the conduct of our clinical trials are not our employees, and we cannot control the amount or timing of resources that they devote to our product development programs. If any of these third parties fails to devote sufficient care, time and resources to our product development programs, if its performance is substandard, or if any third party is inspected by the FDA and found not to be in compliance with GCPs, it will delay the completion of the clinical trial in which they are involved and the progress of the affected development program. The CROs with which we contract for execution of our clinical trials play a significant role in the conduct of the clinical trials and the subsequent collection and analysis of data. Any failure of the CROs to meet their obligations could adversely affect clinical development of our product candidates. Moreover, the CROs, clinical investigators and other service providers may have relationships with other commercial entities, some of which may have competitive products under development or currently marketed, and our competitive position could be harmed if they assist our competitors. If any of these third parties does not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality or accuracy of the clinical data is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for our product candidates. In addition, while we believe that there are numerous alternative sources to provide these services, we might not be able to enter into replacement arrangements without delays or additional expenditures if we were to seek such alternative sources.

We rely on third-party manufacturers to produce our product candidates, which may result in delays in our clinical trials and the commercialization of products, as well as increased costs.

We have no manufacturing facilities, and we do not intend to develop facilities for the manufacture of our product candidates for clinical trials or commercial purposes in the foreseeable future. We contract with third-party manufacturers to produce, in collaboration with us, sufficient quantities of our product candidates for clinical trials, and we plan to contract with third-party manufacturers to produce sufficient quantities of any

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product candidates approved by the FDA or other regulatory authorities for commercial sale. While we believe that there are competitive sources available to manufacture our product candidates, we may not be able to enter into arrangements without delays or additional expenditures. We cannot estimate these delays or costs with certainty.

Reliance on third-party manufacturers limits our ability to control certain aspects of the manufacturing process and therefore exposes us to a variety of significant risks, including risks related to our ability to commercialize any products approved by regulatory authorities or conduct clinical trials, reliance on such third parties for regulatory compliance and quality assurance, and the refusal or inability of a third-party manufacturer to supply our requirements on a long-term basis. In addition, manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel and compliance with federal, state and foreign regulations. Also, our manufacturers may not perform as agreed. If our manufacturers were to encounter any of these difficulties, our ability to timely produce our product candidates for clinical trials and commercial sale may be interrupted, which could result in delayed clinical trials or receipt of regulatory approval and lost or delayed revenues.

To date, we have entered into an agreement with Hospira Worldwide, Inc. for the development and supply of finished product of MN-221 for the treatment of acute exacerbations of asthma utilizing Hospira s proprietary ADD-Vantage drug delivery system that we intend to use in clinical trials and the commercial market if MN-221 receives regulatory approval. In addition to Hospira s proprietary drug delivery system, we anticipate entering into a commercial supply agreement for finished product of MN-221 in standard vials. However, other than Hospira, we do not have agreements established regarding commercial supply of finished product of MN-221 in standard vials or for the active pharmaceutical ingredient, or API, or finished product for any of our product candidates. In particular, pursuant to our license agreement with Kissei Pharmaceutical Co. Ltd., Kissei Pharmaceutical has the exclusive right to manufacture the commercial supply of the API for MN-221. Therefore, we will need to successfully negotiate a commercial supply agreement with Kissei Pharmaceutical on commercially reasonable terms, or another third-party manufacturer in the event that we are unable to reach agreement with Kissei Pharmaceutical, in order to manufacture the API for MN-221 on a commercial scale if MN-221 is approved by the FDA or other regulatory authorities for commercial sale. We will also need to successfully negotiate a supply agreement with a third-party manufacturer on commercially reasonable terms in order to manufacture the finished product of MN-221 in standard vials. We may not be able to establish or maintain any commercial manufacturing and supply arrangements on commercially reasonable terms that we require for purposes of commercializing a product. Any failure by us to secure or maintain any such required commercial supply agreements could result in interruption of supply and lost or delayed revenues, which would adversely affect our business.

Any problems or delays we experience in preparing for commercial-scale manufacturing of a product candidate may result in a delay in FDA or other regulatory approval of the product candidate or may impair our ability to manufacture commercial quantities, which would adversely affect our business. For example, our manufacturers will need to produce specific batches of a product candidate to demonstrate acceptable stability under various conditions and for commercially viable lengths of time. We and our third-party manufacturers will need to demonstrate to the FDA and other regulatory authorities this acceptable stability data for the product candidate, as well as validate methods and manufacturing processes, in order to receive regulatory approval to commercialize such product candidate.

Our manufacturers are obligated to operate in accordance with FDA-mandated current good manufacturing practices, or cGMPs and, in some cases, International Convention on Harmonization, or ICH, standards. A failure of any of our third-party manufacturers to establish and follow cGMPs and/or ICH standards and to document their adherence to such practices may lead to significant delays in our ability to timely conduct and complete clinical trials, obtain regulatory approval of product candidates or launch of our products into the market. In

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addition, changing third-party manufacturers is difficult. For example, a change in third-party manufacturer for a particular product candidate requires re-validation of the manufacturing processes and procedures in accordance with cGMPs, which may be costly and time-consuming and, in some cases, our manufacturers may not provide us with adequate assistance to transfer the manufacturing processes and procedures for our product candidates to new manufacturers or may possess intellectual property rights covering parts of these processes or procedures for which we may need to obtain a license. Failure by our third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of regulatory approvals, seizures or recalls of products, operating restrictions and criminal prosecutions.

We may not be able to manufacture our product candidates in commercial quantities, which would prevent us from commercializing our product candidates.

To date, our product candidates have been manufactured in small quantities for preclinical studies and clinical trials. If any of our product candidates is approved by the FDA or comparable regulatory authorities in other countries for commercial sale, we will need to manufacture such product candidate in larger quantities. We may not be able to increase successfully the manufacturing capacity for any of our product candidates in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. If we are unable to increase successfully the manufacturing capacity for a product candidate, the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage in supply. Our product candidates require precise, high quality manufacturing. Our failure to achieve and maintain these high manufacturing standards in collaboration with our third-party manufacturers, including the incidence of manufacturing errors, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could harm our business, financial condition and results of operations.

Materials necessary to manufacture our product candidates may not be available on commercially reasonable terms, or at all, which may delay the development and commercialization of our product candidates.

We rely on the third-party manufacturers of our product candidates to purchase from third-party suppliers the materials necessary to produce the API and product candidates for our clinical trials, and we will rely on such manufacturers to purchase such materials to produce the API and finished product for any commercial distribution of our products if we obtain marketing approval. Suppliers may not sell these materials to our manufacturers at the time they need them in order to meet our required delivery schedule or on commercially reasonable terms, if at all. We do not have any control over the process or timing of the acquisition of these materials by our manufacturers. Moreover, we currently do not have any agreements for the production of these materials. If our manufacturers are unable to obtain these materials for our clinical trials, testing of the affected product candidate would be delayed, which may significantly impact our ability to develop the product candidate. If we or our manufacturers are unable to purchase these materials after regulatory approval has been obtained for one of our products, the commercial launch of such product would be delayed or there would be a shortage in supply of such product, which would harm our ability to generate revenues from such product and achieve or sustain profitability.

Even if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties.

Even if U.S. regulatory approval is obtained, the FDA may still impose significant restrictions on a product s indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies, including additional research and development and clinical trials. Any of these restrictions or requirements could adversely affect our potential product revenues. For example, the label ultimately approved for MN-221 or MN-166/AV411, our other product candidates or any other product candidates that we may in-license or acquire, if any, may include a restriction on the terms of its use, or it may not include one or more of our intended indications.

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Our product candidates will also be subject to ongoing FDA requirements for the labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information on the drug. In addition, approved products, manufacturers and manufacturers facilities are subject to continual review and periodic inspections. If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If our product candidates fail to comply with applicable regulatory requirements, such as commercial good manufacturing practices, or cGMPs, a regulatory agency may:

- issue warning letters or untitled letters;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- impose other civil or criminal penalties;
- suspend regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require a product recall.

Our product candidates, if approved for sale, may not gain acceptance among physicians, patients and the medical community, thereby limiting our potential to generate revenues.

If one of our product candidates is approved for commercial sale by the FDA or other regulatory authorities, the degree of market acceptance of any approved product by physicians, healthcare professionals and third-party payors and our profitability and growth will depend on a number of factors, including:

- demonstration of efficacy;
- changes in the standard of care for the targeted indication;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;

availability, cost and potential advantages of alternative treatments, including less expensive generic drugs;

pricing and cost effectiveness, which may be subject to regulatory control;

effectiveness of our or any of our partners sales and marketing strategies;

the product labeling or product insert required by the FDA or regulatory authority in other countries; and

the availability of adequate third-party insurance coverage or reimbursement.

If any product candidate that we develop does not provide a treatment regimen that is as beneficial as, or is perceived as being as beneficial as, the current standard of care or otherwise does not provide patient benefit, that product candidate, if approved for commercial sale by the FDA or other regulatory authorities, likely will not achieve market acceptance. Our ability to effectively promote and sell any approved products will also depend on pricing and cost-effectiveness, including our ability to produce a product at a competitive price and our ability to obtain sufficient third-party coverage or reimbursement. If any product candidate is approved but does not

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achieve an adequate level of acceptance by physicians, patients and third-party payors, our ability to generate revenues from that product would be substantially reduced. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

If our products are not accepted by the market or if users of our products are unable to obtain adequate coverage of and reimbursement for our products from government and other third-party payors, our revenues and profitability will suffer.

Our ability to commercialize our products successfully will depend in significant part on pricing and cost effectiveness, including our ability to produce a product at a competitive price and our ability to obtain appropriate coverage of and reimbursement for our products and related treatments from governmental authorities, private health insurers and other organizations, such as health maintenance organizations, or HMOs. Third-party payors are increasingly challenging the prices charged for medical products and services. We cannot provide any assurances that third-party payors will consider our products cost-effective or provide coverage of and reimbursement for our products, in whole or in part.

Uncertainty exists as to the coverage and reimbursement status of newly approved medical products and services and newly approved indications for existing products. Third-party payors may conclude that our products are less safe, less clinically effective or less cost-effective than existing products, and third-party payors may not approve our products for coverage and reimbursement. If we are unable to obtain adequate coverage of and reimbursement for our products from third-party payors, physicians may limit how much or under what circumstances they will prescribe or administer them. Such reduction or limitation in the use of our products could cause our sales to suffer. Even if third-party payors make reimbursement available, payment levels may not be sufficient to make the sale of our products profitable.

Also, continuing health care reform in the U.S. will control or significantly influence the purchase of medical services and products, and may result in inadequate coverage of and reimbursement for our products. Many third-party payors are pursuing various ways to reduce pharmaceutical costs, including the use of formularies. The market for our products depends on access to such formularies, which are lists of medications for which third-party payors provide reimbursement. These formularies are increasingly restricted, and pharmaceutical companies face significant competition in their efforts to place their products on formularies. This increased competition has led to a downward pricing pressure in the industry. The cost containment measures that third-party payors, including government payors, are instituting could have a material adverse effect on our ability to operate profitably.

If we fail to identify and license or acquire other product candidates, we will not be able to expand our business over the long term.

Because we do not have internal discovery capabilities, our business over the long term is substantially dependent on our ability to license or acquire product candidates and further develop them for commercialization. The success of this strategy depends upon our ability to identify, select and acquire the right product candidates. We have limited experience identifying, negotiating and implementing economically viable product candidate acquisitions or licenses, which is a lengthy and complex process. Also, the market for licensing and acquiring product candidates is intensely competitive, and many of our competitors have greater resources than we do. We may not have the requisite capital resources to consummate product candidate acquisitions or licenses that we identify to fulfill our strategy.

Moreover, product candidate acquisitions that we do complete involve numerous risks, including:

- difficulties in integrating the development program for the acquired product candidate into our existing operations;
- diversion of financial and management resources from existing operations;

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risks of entering new markets or technologies and of receiving regulatory approval;

inability to generate sufficient revenues to offset acquisition costs; and

delays that may result from our having to perform unanticipated preclinical trials or other tests on the product candidate.

If we are not successful in identifying and licensing or acquiring other product candidates over the long term, we will not be able to grow our revenues with sales from new products beyond those revenues, if any, from any approved products derived from our existing product candidates, and we may fail to achieve or sustain profitability.

We are dependent on our management team, Yuichi Iwaki, M.D., Ph.D., and experienced scientific staff, and if we are unable to retain, motivate and attract key personnel, our product development programs may be delayed and we may be unable to develop successfully or commercialize our product candidates.

We are dependent upon the continued services of our executive officers and other key personnel, particularly Yuichi Iwaki, M.D., Ph.D., a founder of the company and our President and Chief Executive Officer, who has been instrumental in our ability to in-license product candidates from Japanese pharmaceutical companies and secure financing from Japanese institutions. The relationships that certain of our key managers have cultivated with pharmaceutical companies from whom we license product candidates and to whom we expect to out-license product candidates make us particularly dependent upon their continued services with us, whether through employment, service on our board of directors or a consulting agreement. We are also substantially dependent on the continued services of clinical development personnel because of the highly technical nature of our product development programs. We are not presently aware of any plans of our executive officers or key personnel to retire or leave employment with the company. Each of our executive officers is party to an employment agreement that continues in effect until the earliest of termination of employment upon (i) consent of the parties, (ii) cause or other material breach of the agreement, (iii) death or permanent disability and (iv) three months written notice. Following termination of employment, these individuals may engage in other businesses that may compete with us.

If we acquire or license new product candidates, our success will depend on our ability to attract, retain and motivate highly qualified management and scientific personnel to manage the development of these new product candidates. In particular, our product development programs depend on our ability to attract and retain highly experienced clinical development and regulatory personnel. However, we face competition for experienced scientists and other technical and professional personnel from numerous companies and academic and other research institutions. Competition for qualified personnel is particularly intense in the San Diego, California area, where our corporate headquarters is located. Our short operating history and the uncertainties attendant to being a development-stage biopharmaceutical company could impair our ability to attract and retain personnel and impede the achievement of our development and commercialization objectives. In addition, we have scientific and clinical advisors who assist us in our product development and clinical strategies. These third parties are not our employees and may have commitments to, or contracts with, other entities that may limit their availability to us, or may have arrangements with other companies to assist in the development of products that may compete with our product candidates.

Although we have employment agreements with key members of management, each of our employees, subject to applicable notice requirements, may terminate his or her employment at any time. We do not carry key person insurance covering members of senior management. If we lose any of our key management personnel, we may not be able to find suitable replacements, which would adversely affect our business.

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If we are unable to establish our sales and distribution capabilities, we will be unable to successfully commercialize our product candidates.

To date, we have not sold, marketed or distributed any pharmaceutical products. If we are successful in obtaining regulatory approvals for any of our product candidates or acquiring other approved products, we will need to establish sales, marketing and distribution capabilities on our own or with partners in order to commercialize an approved product. The acquisition or development of an effective sales and marketing infrastructure will require a significant amount of our financial resources and time and could negatively impact our commercialization efforts, including delay of a product launch. We may be unable to establish and manage a sufficient or effective sales force in a timely or cost-effective manner, if at all, and any sales force we do establish may not be capable of generating demand for our products, therefore hindering our ability to generate revenues and achieve or sustain profitability. In addition, if we are unable to develop internal sales capabilities, we will need to contract with third parties or establish a partnership to market and sell the product. If we are unable to establish adequate sales and marketing capabilities, whether independently or with third parties, we may not be able to generate any product revenues, may generate increased expenses and may never become profitable. In addition, although we intend to establish strategic collaborations to market any products approved for sale by regulatory authorities outside of the United States, we may be required to market our product candidates outside of the United States directly if we are unable to establish such collaborations. In that event, we may need to build a corresponding international sales and marketing capability with technical expertise and with supporting distribution capabilities.

Health care reform measures could adversely affect our business.

The business and financial condition of pharmaceutical and biotechnology companies are affected by the efforts of governmental and third-party payers to contain or reduce the costs of health care. In the United States and in foreign jurisdictions, there have been, and we expect that there will continue to be, a number of legislative and regulatory proposals aimed at changing the health care system. For example, in some countries, pricing of prescription drugs is subject to government control, and we expect proposals to implement similar controls in the United States to continue. Another example of proposed reform that could affect our business is drug reimportation into the United States. Moreover, the pendency or approval of such proposals could result in a decrease in our stock price or our ability to raise capital or to obtain strategic partnerships or licenses. More recently, the President signed into law the Patient Protection and Affordable Care Act, which imposes numerous provisions over a four-year period. We have begun to assess the impact of this Act, but, at this early stage the likely impact cannot be ascertained with any degree of certainty.

We may be sued for product liability, which could result in substantial liabilities that exceed our available resources and damage our reputation.

The development and commercialization of drug products entails significant product liability risks. Product liability claims may arise from use of any of our product candidates in clinical trials and the commercial sale of any approved products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

withdrawal of clinical trial participants;

termination of clinical trial sites or entire clinical trial programs;

decreased demand for our product candidates;

impairment of our business reputation;

costs of related litigation;

substantial monetary awards to patients or other claimants;

loss of revenues; and

the inability to commercialize our product candidates.

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We currently have insurance that covers our clinical trials. We believe our current insurance coverage is reasonably adequate at this time; however, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for all expenses or losses we may suffer. In addition, we will need to increase and expand this coverage as we commence additional clinical trials, as well as larger scale clinical trials, and in the event that any of our product candidates is approved for commercial sale. This insurance may be prohibitively expensive or may not fully cover our potential liabilities. In addition, our inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the regulatory approval or commercialization of products that we or one of our collaborators develop. Successful product liability claims could have a material adverse effect on our business and results of operations. Liability from such claims could exceed our total assets if we do not prevail in any lawsuit brought by a third party alleging that an injury was caused by one of our product candidates.

We may need to increase the size of our organization, and we may encounter difficulties managing our growth, which could adversely affect our results of operations.

As of May 10, 2011, we had 17 full-time employees, following a reduction in force which took place in January 2011, wherein we down-sized the company to save costs. If we are successful in securing a strategic collaboration or raising additional capital, our management, personnel, systems and facilities currently in place may not be adequate to support the company s needs. For example, we may hire additional personnel in clinical development, regulatory affairs and business development to further strengthen our core competencies or choose to develop sales, marketing and distribution capabilities for certain of our product candidates. Our need to effectively manage our operations, growth and product development programs requires that we:

- manage our clinical trials effectively;
- manage our internal development efforts effectively while carrying out our contractual obligations to licensors and other third parties;
- ensure that our consultants, CROs and other service providers successfully carry out their contractual obligations, provide high quality results and meet expected deadlines; and
- continue to improve our operational, financial and management controls, reporting systems and procedures.

We may be unable to successfully implement these tasks on a larger scale, which may impact our ability to timely achieve our development and commercialization goals, if at all.

We expect that our results of operations will fluctuate, which may make it difficult to predict our future performance from period to period.

Our quarterly operating results have fluctuated in the past and are likely to continue to do so in the future. Some of the factors that could cause our operating results to fluctuate from period to period include:

- the status of development of our product candidates and, in particular, the advancement or termination of activities related to our product development programs and the timing of any milestone payments payable under our licensing agreements;
- the execution of other collaboration, licensing and similar arrangements and the timing of payments we may make or receive under these arrangements;
- variations in the level of expenses related to our product development programs;

the unpredictable effects of collaborations during these periods;

the timing of our satisfaction of applicable regulatory requirements, if at all;

the rate of expansion of our clinical development and other internal research and development efforts;

the costs of any litigation;

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the effect of competing technologies and products and market developments; and

general and industry-specific economic conditions.

We believe that quarterly or yearly comparisons of our financial results are not necessarily meaningful and should not be relied upon as indications of our future performance.

Our management has broad discretion over the use of our cash, and we may not use our cash effectively, which could adversely affect our results of operations.

Our management has significant flexibility in applying our cash resources and could use these resources for corporate purposes that do not increase our market value or in ways with which our stockholders may not agree. We may use our cash resources for corporate purposes that do not yield a significant return or any return at all for our stockholders, which may cause our stock price to decline.

We will continue to incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we are required to comply with the Sarbanes-Oxley Act of 2002, as well as rules and regulations implemented by the SEC, The Nasdaq Stock Market, or Nasdaq, and Japanese securities laws, and incur significant legal, accounting and other expenses as a result. These rules impose various requirements on public companies, including requiring the establishment and maintenance of effective disclosure and financial controls and appropriate corporate governance practices. Our management and other personnel have devoted and will continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and may make it more difficult and expensive for us to renew our director and officer liability insurance, and result in imposition of reduced policy limits and coverage.

The Sarbanes-Oxley Act requires that we maintain effective internal controls for financial reporting and disclosure controls and procedures. Our listing obligations under the Jasdaq Market (formerly the Hercules Market until its closure in 2010) of the Osaka Securities Exchange, or OSE, also require that we comply either with Section 404 of the Sarbanes-Oxley Act or equivalent regulations in Japan and we elected to comply with Section 404. As a result, we are required to perform an evaluation of our internal control over financial reporting to allow management to report on the effectiveness of those controls, as required by Section 404. We are subject to attestation by our registered public accounting firm on our report regarding internal control over financial reporting for the year ended December 31, 2010 under Japanese securities laws. Our efforts to comply with Section 404 and related regulations have required, and continue to require, the commitment of significant financial and managerial resources. We cannot be certain that a material weakness will not be identified when we test the effectiveness of our controls in the future. If a material weakness is identified, we could be subject to sanctions or investigations by Nasdaq, the SEC, the OSE or other regulatory authorities, which would require additional financial and management resources, costly litigation or a loss of public confidence in our internal controls, which could have an adverse effect on the market price of our stock.

We identified a material weakness in our internal control over financial reporting, and any failure to effectively remediate the material weakness identified as of September 30, 2010 could result in material misstatements in our financial statements.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting that creates a reasonable possibility that a material misstatement of our interim or annual financial statements will not be prevented or detected on a timely basis. In the course of carrying out the required quarterly evaluation and preparing the financial statements as of September 30, 2010, management identified control overrides and policy deviations by one of our senior executive officers. The following deficiencies in internal

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control over financial reporting, which collectively represented a material weakness in our internal control over financial reporting, were reported by management to our Audit Committee:

- A senior executive officer lacked a sufficient control awareness related to compliance with our Code of Conduct, contract review and approval policies, and certain human resources policies and procedures for employee terminations.

- We did not design adequate human resources policies and procedures related to ensuring compliance with our Code of Conduct.

Our management team is committed to achieving and maintaining a strong control environment and an overall tone within the organization that empowers all employees to act with the highest standards of ethical conduct. In addition, management remains committed to the process of developing and implementing improved corporate governance and compliance initiatives. Our Board and management team implemented the following remediation plan to address the material weakness and enhance our internal controls:

- The Board revised our contract review and approval policy to require the signature of two executive officers, one of whom must be the Chief Financial Officer or his designee;

- The Board assigned additional responsibility to the Compensation Committee, including requirements that the Compensation Committee approve (1) any salary increases/adjustments greater than 10%, (2) any promotion or hiring into any position at the level of Vice President or above, (3) the salary of any individual promoted or hired for any position at the level of Vice President or above and (4) the granting to any employee of benefits or other perquisites not generally available to all employees;

- The Board changed the reporting lines of our Vice President of Clinical Development and our Manager of Human Resources and Administration; and

- Due to the appearance of a possible conflict of interest, the Board granted a waiver under our Code of Conduct to a senior executive officer and one of our other employees with respect to any joint real estate and banking transactions to which they are party as of November 13, 2010.

In addition, subsequent to September 30, 2010, our Board formed a Strategic and Operational Review Committee comprised of certain members of our Board and our senior management team that has been tasked with reviewing all key strategic and operational matters. Our Board and our senior management team may engage additional third-party specialists to further review and identify any other enhancements to our internal controls that may help prevent future significant deficiencies and/or material weaknesses.

We have tested our remediation plan with the assistance of a third party and we have conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2010. The framework on which such evaluation was based is contained in the report entitled Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO Report). Based on our evaluation under the criteria set forth in the COSO Report, our management concluded our internal control over financial reporting was effective as of December 31, 2010. Our registered public accounting firm issued an audit report on the effectiveness of our internal control over financial reporting as of December 31, 2010 wherein they opined on the effectiveness of our internal control over financial reporting as of December 31, 2010. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

If significant deficiencies or additional material weaknesses in our internal control are discovered or occur in the future, we may fail to meet our future reporting obligations on a timely basis, our consolidated financial statements may contain material misstatements, we could be required to restate our prior period financial results, our operating results may be harmed, we may be subject to class action litigation and, our common stock could be delisted from Nasdaq and the Jasdaq Market of the OSE.

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Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our drug development programs, including delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability and the further development of our product candidates may be delayed.

We may not realize all of the anticipated benefits of the combined clinical development programs based on ibudilast.

We may not be able to successfully secure a strategic collaboration to advance the combined ibudilast development programs. Following completion of the Phase 2 clinical trial of MN-166 for the treatment of MS in the second quarter of 2008 and the acquisition of AV411 in December 2009, we have not undertaken, nor do we plan to undertake, any further significant clinical development of MN-166/AV411 until such time that we secure a strategic collaboration to advance the combined clinical development of MN-166/AV411 ibudilast-based development program. We cannot assure you that we will be able to secure such a strategic collaboration or otherwise further advance, or recognize value from, a combined MN-166/AV411 clinical development program.

Risks Related to Our Intellectual Property

Our ability to compete may decline if we do not adequately protect our proprietary rights.

There is the risk that our patents (both those owned by us and those in-licensed) may not provide a competitive advantage, including the risk that our patents expire before we obtain regulatory and marketing approval for one or more of our product candidates, particularly our in-licensed patents. Also, our competitors may develop products similar to ours using methods and technologies that are beyond the scope of our intellectual property rights. Composition of matter patents on APIs may provide protection for pharmaceutical products without regard to formulation, method of use, or other type of limitation. We do not have compound patent protection for the API in our MN-166/AV411 and MN-001 product candidates, although we do have patent protection for a particular crystalline polymorph of MN-001 and we have composition of matter protection on ibudilast analogs. As a result, competitors that obtain the requisite regulatory approval will be able to offer products with the same API as found in our MN-166/AV411 and MN-001 product candidates so long as such competitors do not infringe any methods of use, methods of manufacture, formulation or, in the case of MN-001, specific polymorph patents that we hold or have exclusive rights to through our licensors. For example, we currently rely on a method of use patent for MN-166, which covers the use of the API found in our MN-166 product candidate for the treatment of MS. We also have a method of use patent for AV411 for the treatment of neuropathic pain syndromes.

It is our policy to consult with our licensors in the maintenance of granted patents we have licensed and in their pursuit of patent applications that we have licensed, but each of our licensors generally remains primarily responsible for or in control of the maintenance of the granted patents and prosecution of the applications. We have limited control, if any, over the amount or timing of resources that each licensor devotes on our behalf, and a licensor may not assign as great a priority to prosecution of these patent applications as we would if we were undertaking such prosecution ourselves. As a result of this lack of control and general uncertainties in the patent prosecution process, we cannot be sure that our licensed patents will be maintained and that any additional patents will ever mature from our licensed applications. Issued U.S. patents require the payment of maintenance fees to continue to be in force. We typically rely on our licensors to do this and their failure to do so could result in the forfeiture of patents not timely maintained. Many foreign patent offices also require the payment of periodic annuities to keep patents and patent applications in good standing. As we generally do not maintain

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control over the payment of annuities, we cannot be certain that our licensors will timely pay such annuities and that the granted patents and pending patent applications will not become abandoned. For example, certain annuities were not paid in a timely manner with respect to foreign patents licensed under MN-002 (the active metabolite of MN-001) and, as a result, our patent rights may be impaired in those territories. In addition, our licensors may have selected a limited amount of foreign patent protection, and therefore applications have not been filed in, and foreign patents may not have been perfected in, all commercially significant countries.

The patent protection of our product candidates and technology involves complex legal and factual questions. Most of our license agreements give us a right, but not an obligation, to enforce our patent rights. To the extent it is necessary or advantageous for any of our licensors cooperation in the enforcement of our patent rights, we cannot control the amount or timing of resources our licensors devote on our behalf or the priority they place on enforcing our patent rights. We may not be able to protect our intellectual property rights against third party infringement, which may be difficult to detect, especially for infringement of patent claims for methods of manufacturing. Additionally, challenges may be made to the ownership of our intellectual property rights, our ability to enforce them or our underlying licenses, which in some cases have been made under foreign laws and may provide different protections than that of U.S. law.

We cannot be certain that any of the patents or patent applications owned by us or our licensors related to our product candidates and technology will provide adequate protection from competing products. Our success will depend, in part, on whether we or our licensors can:

- obtain and maintain patents to protect our product candidates;
- obtain and maintain any required or desirable licenses to use certain technologies of third parties, which may be protected by patents;
- protect our trade secrets and know-how;
- operate without infringing the intellectual property and proprietary rights of others;
- enforce the issued patents under which we hold rights; and
- develop additional proprietary technologies that are patentable.

The degree of future protection for our proprietary rights is uncertain. For example:

- we or our licensor might not have been the first to make the inventions covered by each of our pending patent applications or issued patents;
- we or our licensor might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that none of our pending patent applications will result in issued patents;

any patents under which we hold rights may not provide us with a basis for maintaining market exclusivity for commercially viable products, may not provide us with any competitive advantages or may be challenged by third parties as invalid, not infringed or unenforceable under U.S. or foreign laws; or

any of the issued patents under which we hold rights may not be valid or enforceable or may be circumvented successfully in light of the continuing evolution of domestic and foreign patent laws.

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Confidentiality agreements with employees and others may not adequately prevent disclosure of our trade secrets and other proprietary information and may not adequately protect our intellectual property, which could limit our ability to compete.

Because we operate in the highly technical field of research and development of small molecule drugs, we rely in part on trade secret protection in order to protect our proprietary trade secrets and unpatented know-how. However, trade secrets are difficult to protect, and we cannot be certain that others will not develop the same or similar technologies on their own. We have taken steps, including entering into confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors, to protect our trade secrets and unpatented know-how. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party s relationship with us. We also typically obtain agreements from these parties which provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Further, we have limited control, if any, over the protection of trade secrets developed by our licensors. Enforcing a claim that a party illegally obtained and is using our trade secrets or know-how is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets or know-how. The failure to obtain or maintain trade secret protection could adversely affect our competitive position.

A dispute concerning the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be time consuming and costly, and an unfavorable outcome could harm our business.

There is significant litigation in our industry regarding patent and other intellectual property rights. While we are not currently subject to any pending intellectual property litigation, and are not aware of any such threatened litigation, we may be exposed to future litigation by third parties based on claims that our product candidates, their methods of use, manufacturing or other technologies or activities infringe the intellectual property rights of such third parties. There are many patents relating to chemical compounds and methods of use. If our compounds or their methods of use or manufacture are found to infringe any such patents, we may have to pay significant damages or seek licenses under such patents. We have not conducted comprehensive searches for unexpired patents issued to third parties relating to our product candidates. Consequently, no assurance can be given that unexpired, third-party patents containing claims covering our product candidates, their methods of use or manufacture do not exist. Moreover, because some patent applications in the United States may be maintained in secrecy until the patents are issued, and because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, we cannot be certain that others have not filed patent applications that will mature into issued patents that relate to our current or future product candidates and which could have a material effect in developing and commercializing one or more of our product candidates. The owner of a patent that is arguably infringed can bring a civil action seeking to enjoin an accused infringer from importing, making, marketing, distributing, using or selling an infringing product. We may need to resort to litigation to enforce our intellectual property rights or to seek a declaratory judgment concerning the scope, validity or enforceability of third-party proprietary rights. Similarly, we may be subject to claims that we have inappropriately used or disclosed trade secrets or other proprietary information of third parties. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. We may not be able to afford the costs of litigation. Any legal action against us or our collaborators could lead to:

payment of actual damages, royalties, lost profits, potential enhanced damages and attorneys fees, if any infringement for which we are found liable is deemed willful, or a case against us is determined by a judge to be exceptional;

injunctive or other equitable relief that may effectively block our ability to further develop, commercialize and sell our products;

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having to enter into license arrangements that may not be available on reasonable or commercially acceptable terms; or

significant cost and expense, as well as distraction of our management from our business.

As a result, we could lose our ability to develop and commercialize current or future product candidates.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to the Securities Markets and Investment in Our Common Stock

Our stock price may be volatile, and you may not be able to resell our shares at a profit or at all.

Despite the listing of our common stock on the Nasdaq Global Market and the Jasdaq Market of the Osaka Securities Exchange in Japan, trading volume in our securities has been light and an active trading market may not develop for our common stock. In March 2011, our average trading volume was approximately 1,700 shares per day on the Nasdaq Global Market and approximately 25,000 shares per day on the Jasdaq Market.

The market prices for securities of biopharmaceutical and biotechnology companies, and early-stage drug discovery and development companies like us in particular, have historically been highly volatile and may continue to be highly volatile in the future. For example, since the date of our initial public offering in Japan on February 4, 2005 through March 31, 2011, our common stock has traded as high as approximately $42.00 and as low as approximately $1.40. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

the development status of our product candidates, including clinical trial results and determinations by regulatory authorities with respect to our product candidates, and particularly our prioritized product candidates;

the initiation, termination, or reduction in the scope of any collaboration arrangements or any disputes or developments regarding such collaborations;

FDA or foreign regulatory actions, including failure to receive regulatory approval for any of our product candidates;

announcements of technological innovations, new commercial products or other material events by us or our competitors;

disputes or other developments concerning our intellectual property rights;

market conditions in the pharmaceutical and biotechnology sectors;

actual and anticipated fluctuations in our quarterly or annual operating results;

price and volume fluctuations in the overall stock markets;

any potential delisting of our securities;

changes in, or failure to meet, securities analysts or investors expectations of our financial performance;

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additions or departures of key personnel;

discussions of our business, management, products, financial performance, prospects or stock price by the financial and scientific press and online investor communities;

litigation or public concern about the safety of our potential products;

public concern as to, and legislative action with respect to, the pricing and availability of prescription drugs or the safety of drugs and drug delivery techniques; or

regulatory developments in the United States and in foreign countries.

Broad market and industry factors, as well as economic and political factors, also may materially adversely affect the market price of our common stock.

We may become involved in securities class action litigation that could divert management s attention and harm our business.

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of biotechnology and biopharmaceutical companies. These broad market fluctuations may cause the market price of our common stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management s attention and resources, which could adversely affect our business.

Future sales of our common stock may cause our stock price to decline and may make it difficult to sell your shares.

Sales of substantial amounts of our common stock, or the availability of such common stock for sale, could adversely affect the prevailing market prices for our common stock. If this occurs and continues, it could impair our ability to raise additional capital through the sale of securities should we desire to do so. In addition, it may be difficult, or even impossible, to find a buyer for shares of our common stock.

We have also registered all common stock that we may issue under our current employee benefits plans and upon exercise of warrants. As a result, these shares can be freely sold in the public market upon issuance, subject to the terms of the underlying agreements governing the grants and the restrictions of the securities laws. In addition, our directors and officers may in the future establish programmed selling plans under Rule 10b5-1 of the Exchange Act, for the purpose of effecting sales of our common stock. If any of these events cause a large number of our shares to be sold in the public market, the sales could reduce the trading price of our common stock and impede our ability to raise future capital.

Anti-takeover provisions in our charter documents and under Delaware law and the existence of our stockholder rights plan may make an acquisition of us more complicated and the removal and replacement of our directors and management more difficult.

Our restated certificate of incorporation and amended and restated bylaws contain provisions that may delay or prevent a change in control, discourage bids at a premium over the market price of our common stock or adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. These provisions may also make it difficult for stockholders to remove and replace our board of directors and management. These provisions:

establish that members of the board of directors may be removed only for cause upon the affirmative vote of stockholders owning at least a majority of our capital stock;

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authorize the issuance of blank check preferred stock that could be issued by our board of directors in a discriminatory fashion designed to increase the number of outstanding shares and prevent or delay a takeover attempt;

limit who may call a special meeting of stockholders;

establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings;

prohibit our stockholders from making certain changes to our Restated Certificate of Incorporation or Amended and Restated Bylaws except with 66 2/3 percent stockholder approval; and

provide for a classified board of directors with staggered terms.

In addition, we adopted a stockholder rights plan in November 2006, pursuant to which each share of our common stock includes an attached preferred stock purchase right, that is designed to impede takeover transactions that are not supported by our board of directors.

We also may be subject to provisions of the Delaware corporation law that, in general, prohibit any business combination with a beneficial owner of 15 percent or more of our common stock for three years unless the holder s acquisition of our stock was approved in advance by our board of directors. Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In any event, these provisions may delay or prevent a third party from acquiring us. Any such delay or prevention could cause the market price of our common stock to decline.

We have never paid dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.

We have paid no cash dividends on any of our classes of capital stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. (REMOVED AND RESERVED).

ITEM 5. OTHER INFORMATION.

None.

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ITEM 6. EXHIBITS.

Exhibit Number	Description
4.1(1)	Form of Warrant to Purchase Common Stock.
10.39(2)	Form of Amendment to Employment Agreement between MediciNova, Inc. and certain of its executive officers, dated December 31, 2010.
10.40(2)	Form of Severance Protection Agreement between MediciNova, Inc. and certain of its executive officers, dated December 31, 2010.
10.41(3)	Separation Agreement dated February 1, 2011, by and between MediciNova, Inc. and Shintaro Asako.
10.42	Pay-off Letter dated March 31, 2011, by and between MediciNova, Inc. and Oxford Finance Corporation
31.1	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the period ended March 31, 2011.
31.2	Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the period ended March 31, 2011.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350 (Section 906 of the Sarbanes-Oxley Act of 2002).
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350 (Section 906 of the Sarbanes-Oxley Act of 2002).

(1) Filed with the Registrant s Current Report on Form 8-K filed March 24, 2011 and incorporated herein by reference.
(2) Filed with the Registrant s Current Report on Form 8-K filed January 4, 2011 and incorporated herein by reference.
(3) Filed with the Registrant s Current Report on Form 8-K filed February 3, 2011 and incorporated herein by reference.

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SIGNATURES

Pursuant to the requirements of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

MEDICINOVA, INC.

Date: May 16, 2011

By: /s/ YUICHI IWAKI
Yuichi Iwaki, M.D., Ph.D.

President and Chief Executive Officer

(on behalf of the registrant and

as the registrant s Principal Executive Officer)

By: /s/ MICHAEL COFFEE
Michael Coffee

Chief Business Officer and Interim Chief Financial Officer

(on behalf of the registrant and

as the registrant s Principal Financial Officer)

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